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Environmental Cancer and Heart and Lung Disease

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Rockville, MD

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ENVIRONMENTAL CANCER AND HEART AND LUNG DISEASE

FOURTH ANNUAL REPORT TO CONGRESS

August 7, 1981

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TASK FORCE ON
ENVIRONMENTAL CANCER AND HEART AND LUNG DISEASE

U.S. Environmental Protection Agency • National Cancer Institute
National Heart, Lung, and Blood Institute • National Institute for Occupational Safety and Health
National Institute of Environmental Health Sciences • National Center for Health Statistics
Centers for Disease Control • Food and Drug Administration

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16. Abstract (Limit: 200 words)

This report to Congress presents the activities and accomplishments of the Task Force on Environmental Cancer and Heart and Lung Disease, in its fourth year. Three recommendations are discussed: the implementation and operation of the National Death Index from the National Center for Health Statistics, the study of the impediments to epidemiology research, and the development of a coordinated environmental health education program for clinicians and other health professionals.

Also discussed in this report are the activities and progress of the Task Force Working Group and of the Project Groups: Exposure and Metabolic Mechanisms, Education of the Public and Health Professionals, Standardization and Measurements and Tests. The Project Group on Exposure and Metabolic Mechanisms identified research needs through the consensus of scientists who participated in the Workshop on Exposure Metabolism, and Mechanisms of Toxicity.

The main Task Force activities which are also discussed are: formation of the Interagency Education Liason Group, compilation of a Project Inventory of environment related disease research, initiation of a survey of federally sponsored chemical measurement programs, institution of a feasibility study on the relationship of quality control and quality assurance procedures in the Task Force Agencies, institution of a feasibility study on the relationship of quality control activities to data quality, completion of a background study on public environmental/occupational health education.

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ENVIRONMENTAL CANCER AND HEART AND LUNG DISEASE

Fourth Annual Report to Congress

August 7, 1981

TASK FORCE ON ENVIRONMENTAL CANCER AND HEART AND LUNG DISEASE

U.S. Environmental Protection Agency
National Cancer Institute
National Heart, Lung, and Blood Institute
National Institute for Occupational Safety and Health
National Institute of Environmental Health Sciences
National Center for Health Statistics
Centers for Disease Control
Food and Drug Administration

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Washington, D.C. 20460

Professional support to the Task Force on Environmental Cancer and Heart and Lung Disease is provided by GEOMET Technologies, Inc. (GTI), through EPA Contract Number 68-01-5773; Ms. Roberta A. Cahill is the EPA Project Officer. GTI staff support is under the immediate technical direction of Ms. Peggy L. Young and Mr. Scott D. Thayer.

TASK FORCE ON
ENVIRONMENTAL CANCER AND HEART AND LUNG DISEASE

Please address your reply to:

John W. Hernandez
Deputy Administrator
U.S. Environmental Protection
Agency

July 30, 1981

Honorable Thomas P. O'Neill, Jr.
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

As Chairman of the Task Force on Environmental Cancer and Heart and Lung Disease, I am pleased to submit the Fourth Annual Report to Congress in accordance with Public Law 95-95, Section 402.

There has been substantial progress this year particularly in response to Section 402 (b) (3) recommendations for research, and Sections 402 (b) (4), coordination and cooperation between the Environmental Protection Agency (EPA) and the Department of Health and Human Services (DHHS). Areas of research have been identified for review by Task Force Agencies during the next year for applicable incorporation into existing research programs. An extensive inventory of current Federal research in environmental cancer, heart, and lung disease has been compiled. Analysis of this inventory is under way to assist the Agencies in cost-effective research management.

EPA and DHHS have worked together closely to assure transfer of information and cooperative research efforts where appropriate. These joint efforts are in line with my views that our goals can best be met by a cooperative team approach to solution of problems. It is also a cost-effective approach which is particularly meaningful in these times of fiscal constraint.

I am pleased by the continuing interest of Congress in the work of this Task Force as evidenced by their attendance and comments at the Plenary meeting April 15. I thank all the participants of the Task Force for their hard work and open cooperation during the past year.

We look forward to continuing progress in achieving better understanding of causal relationships in environmental cancer and heart and lung disease.

Sincerely yours,

John W. Hernandez
Chairman
Task Force on Environmental Cancer
and Heart and Lung Disease

PREFACE

The Task Force on Environmental Cancer and Heart and Lung Disease was established by Congress on August 7, 1977, in Section 402 of Public Law 95-95, as part of the Clean Air Act Amendments. The legislatively mandated purpose of the Task Force is to recommend and coordinate Federal research programs aimed at reducing or preventing the incidence of cancer and heart and lung disease caused by environmental factors. As initially constituted, the Task Force included representatives from the U.S. Environmental Protection Agency; the National Cancer Institute; the National Heart, Lung, and Blood Institute; the National Institute for Occupational Safety and Health; and the National Institute of Environmental Health Sciences. The Administrator of the Environmental Protection Agency (or a person delegated by the Administrator) was named to chair the Task Force. The Health Services Research, Health Statistics, and Health Care Technology Act of 1978 (Public Law 96-623) added representatives from the National Center for Health Statistics and the Centers for Disease Control to the Task Force. The Food and Drug Administration was invited to participate in Task Force activities in September 1978; it became a formal member in April 1980 by vote of the Task Force members. The Task Force is required to report annually to Congress on its progress and problems.

This report describes the work of the Task Force in its fourth year (September 1980 to August 1981) and outlines plans for the future. Chapter 1 introduces the Task Force and briefly describes the status of the environmental disease problem. Chapter 2 states the Task Force recommendations to Congress, and Chapter 3 outlines the research needs identified by a Task Force-sponsored workshop. The full scope of Task Force activities for the year is described in Chapter 4. Chapter 5 presents future plans of the Task Force.

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ABBREVIATIONS

CCERP	-	Committee to Coordinate Environmental and Related Programs
CDC	-	Centers for Disease Control
CEQ	-	Council on Environmental Quality
COPD	-	Chronic Obstructive Pulmonary Disease
CPSC	-	Consumer Product Safety Commission
DHHS	-	U.S. Department of Health and Human Services
DNA	-	Deoxyribonucleic Acid
DOD	-	U.S. Department of Defense
DOL	-	U.S. Department of Labor
EPA	-	U.S. Environmental Protection Agency
FDA	-	Food and Drug Administration
FSQS	-	Food Safety and Quality Service
HCFA	-	Health Care Financing Administration
HRA	-	Health Resources Administration
IARC	-	International Agency for Research on Cancer
ICGEC	-	Interagency Collaborative Group on Environmental Carcinogenesis
IEPLG	-	Interagency Education Program Liaison Group
IRLG	-	Interagency Regulatory Liaison Group
IRRC	-	Interagency Radiation Research Committee
NAS/IOM	-	National Academy of Sciences/Institute of Medicine
NBS	-	National Bureau of Standards
NCAQ	-	National Commission on Air Quality
NCHS	-	National Center for Health Statistics
NCI	-	National Cancer Institute
NCVHS	-	National Committee on Vital and Health Statistics
NDI	-	National Death Index
NHLBI	-	National Heart, Lung, and Blood Institute
NIAMDD	-	National Institute of Arthritis, Metabolism, and Digestive Diseases
NIEHS	-	National Institute of Environmental Health Sciences
NIH	-	National Institutes of Health
NIOSH	-	National Institute for Occupational Safety and Health
NOAA	-	National Oceanic and Atmospheric Administration
NSF	-	National Science Foundation
NTIS	-	National Technical Information Service
NTP	-	National Toxicology Program
OHER	-	Office of Health and Environmental Research
OSHA	-	Occupational Safety and Health Administration
QC	-	Quality Control
SCRA	-	Subcommittee to Coordinate Radiation Activities
SEAS	-	Strategic Environmental Assessment System
SSA	-	Social Security Administration
TSCA	-	Toxic Substances Control Act
USDA	-	U.S. Department of Agriculture

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EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

The Clean Air Act Amendments of 1977, which authorize the Task Force on Environmental Cancer and Heart and Lung Disease, stipulate that the Task Force recommend research programs, research strategies, and other measures to reduce or eliminate the risk and incidence of disease caused by environmental pollutants. To fulfill its mandate, the Task Force had to define the problem, review relevant information from many sources, and identify specific areas for concentrated analysis. Activities of the Task Force during its first 2 years provided the groundwork for the recommendations and research needs identified during the Task Force third and fourth years.

RECOMMENDATIONS TO CONGRESS

The Task Force Plenary and Working Group members approved three major recommendations to Congress this year. Two of the recommendations are intended to facilitate epidemiological research, which studies population groups with known or suspected exposures to various agents.

> RECOMMENDATION 1. A high priority should be given to the implementation and continued operation of the National Death Index being developed under the auspices of the National Center for Health Statistics.
>
> RECOMMENDATION 2. Legal impediments to both Federal and non-Federal epidemiology research should be studied further.

The third recommendation recognizes the lack of awareness among health professionals of environment- and work-related factors that may contribute to disease.

RECOMMENDATION 3. The development of a coordinated environmental health education program for clinicians and health professionals should be fostered.

RESEARCH NEEDS FOR REVIEW BY FEDERAL AGENCIES

The Task Force Project Group on Exposure and Metabolic Mechanisms identified specific research needs through the consensus of scientists who participated in the Workshop on Exposure, Metabolism, and Mechanisms of Toxicity. The identified research needs, listed in Chapter 3 of this report, are oriented to specific subject areas: (1) epidemiology, (2) quantification of exposure, (3) methods for monitoring individual human exposures, (4) metabolism, (5) in vivo toxicity, (6) mechanisms of toxicity/carcinogenicity. Detailed discussion and full rationale for the research needs are contained in the workshop document, Summary of the Workshop on Exposure to Environmental Agents, Their Metabolism, and Mechanisms of Toxicity: Research Needs. The Task Force Working Group will direct these research needs to the appropriate Agencies for their review and consideration during the coming year.

ACCOMPLISHMENTS OF THE FOURTH YEAR

In addition to the congressional recommendations and the Workshop described above, the following major Task Force activities have resulted in reports and significant findings for Agency review and evaluation:

- Formation of the Interagency Education Program Liaison Group (IEPLG)
  - Coordinates health professional educational programs in environmental/occupational health

- Search of Agency data bases to compile the Project Inventory of environment-related disease research

  - Aids Agency planning processes by identifying specific research projects in the eight Federal Task Force Agencies

- Initiation of a survey of federally sponsored chemical measurement programs

  - Fosters compatibility of quality control and quality assurance procedures in the Task Force Agencies

- Institution of a feasibility study on the relationship of quality control activities to data quality

  - Promotes allocation of resources for quality control

- Completion of a background study on public environmental/occupational health education

  - Identifies the problem in disseminating health education materials.

The Task Force information exchange activities provide important means of interagency coordination and information dissemination among the Federal Agencies and scientific community. Current information exchange activities initiated by the Task Force include the following:

- The monthly Task Force Calendar of Events alerts more than 1,000 subscribers to various meetings and courses related to environmental health.

- The annual Directory of Federal Interagency Groups Concerned with Environmental Health provides specific information on members, activities, and reports in areas relevant to the Task Force mission.

- The Directory of Exposure-Related Data Bases facilitates access to data on human exposure to environmental pollutants.

- The tracking of a groundwater research recommendation from its conception through to its implementation enables the evaluation of the responsiveness of program recommendations.

The Task Force devotes major effort to the development and promotion of interagency coordination through formal liaison with other interagency groups and the distribution of its reports and findings. The Task Force Project Inventory and annual reports can effectively aid Agency planning processes.

The Task Force continues to build on its past accomplishments and follow up its recommendations to Congress and the Federal Agencies. By analyzing its progress and maintaining an awareness of related activities both within and outside of the Government, the Task Force continues to provide information, recommendations, and ideas for improvements in research. During the coming months, the Task Force will act to address other aspects of their legislative mandate to "recommend a comprehensive research program..." and "...comprehensive strategies"* aimed at reducing or eliminating the incidence and occurrence of environmentally induced cancer and heart and lung diseases.

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*Public Law 95-95, Section 402(b)(1 and 2).

Chapter 1

INTRODUCTION

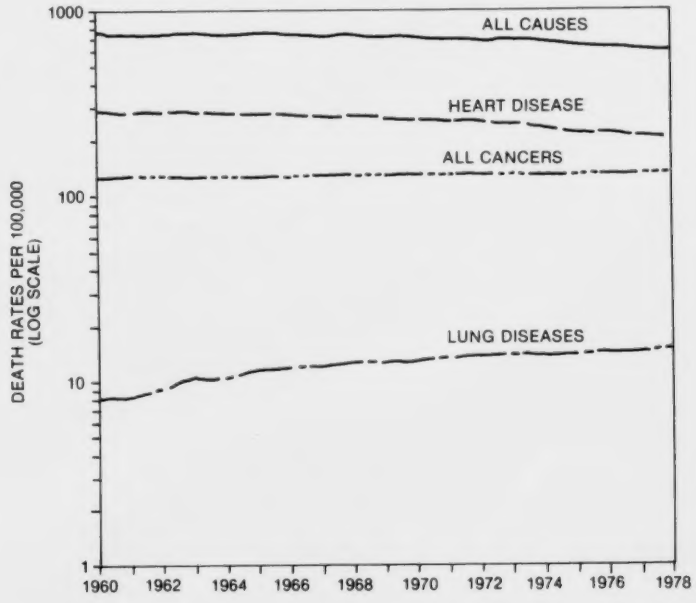
Chapter 1

INTRODUCTION

THE PROBLEM

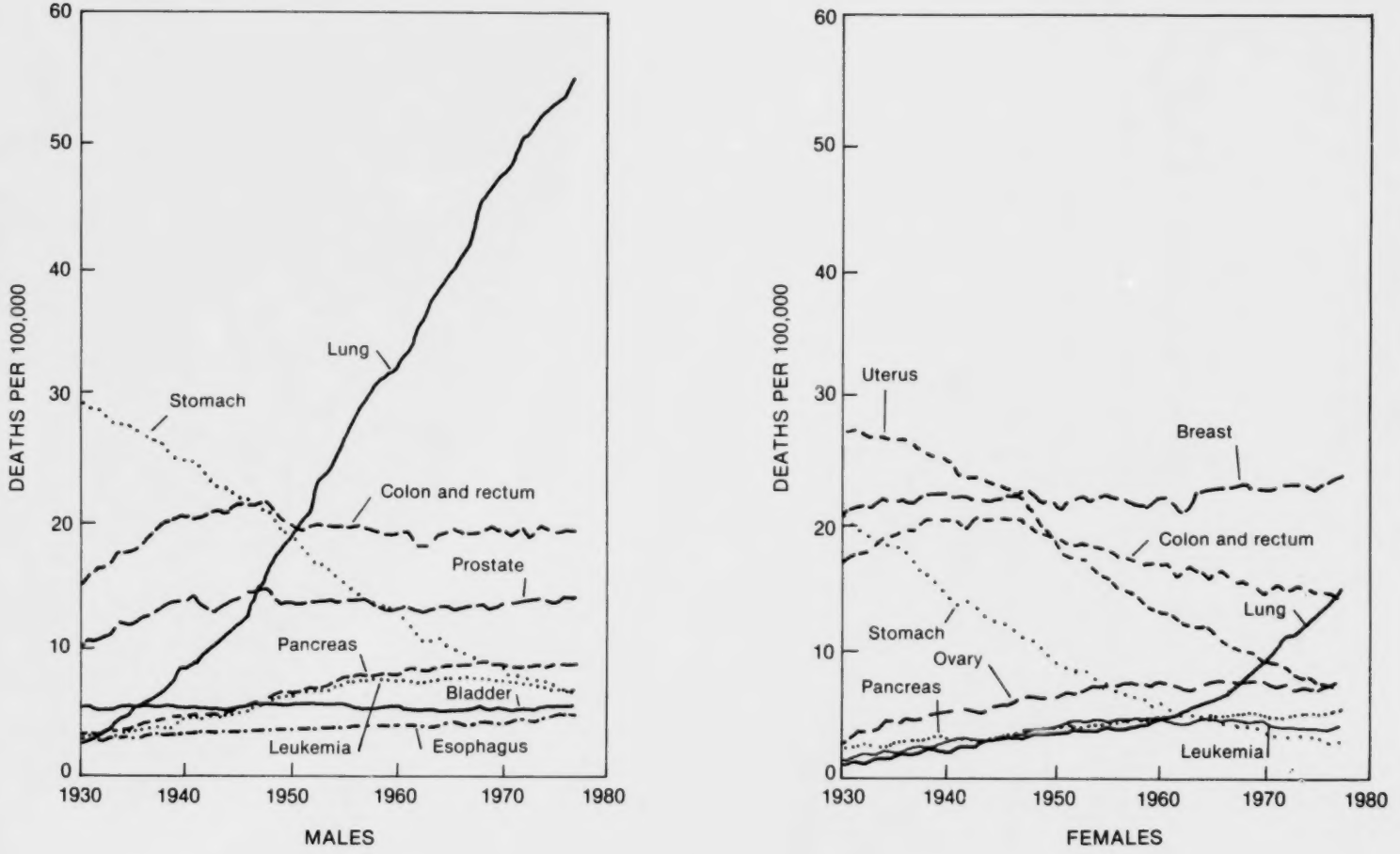
The recognition that agents in the environment can cause disease was the impetus that led Congress to create the Task Force on Environmental Cancer and Heart and Lung Disease. Heart disease is the leading cause of death in the United States, with cancer (malignant neoplasms) second and lung (respiratory) diseases fifth. A substantial proportion of these deaths is believed to be associated with environmental factors.

These statistics are impressive, yet the age-adjusted death rate for heart disease has actually been decreasing (Figure 1), partly because of advances in preventive health and improved clinical care and treatment. Figure 1 also shows a slight increase in overall cancer mortality; selected site-specific changes in cancer mortality are shown in Figure 2.



Source: Vital Statistics of the United States, Vol. 2, Mortality. National Center for Health Statistics. (Published annually.)

Figure 1. Age-adjusted Death Rates for Selected Causes of Death, United States, 1960-1978

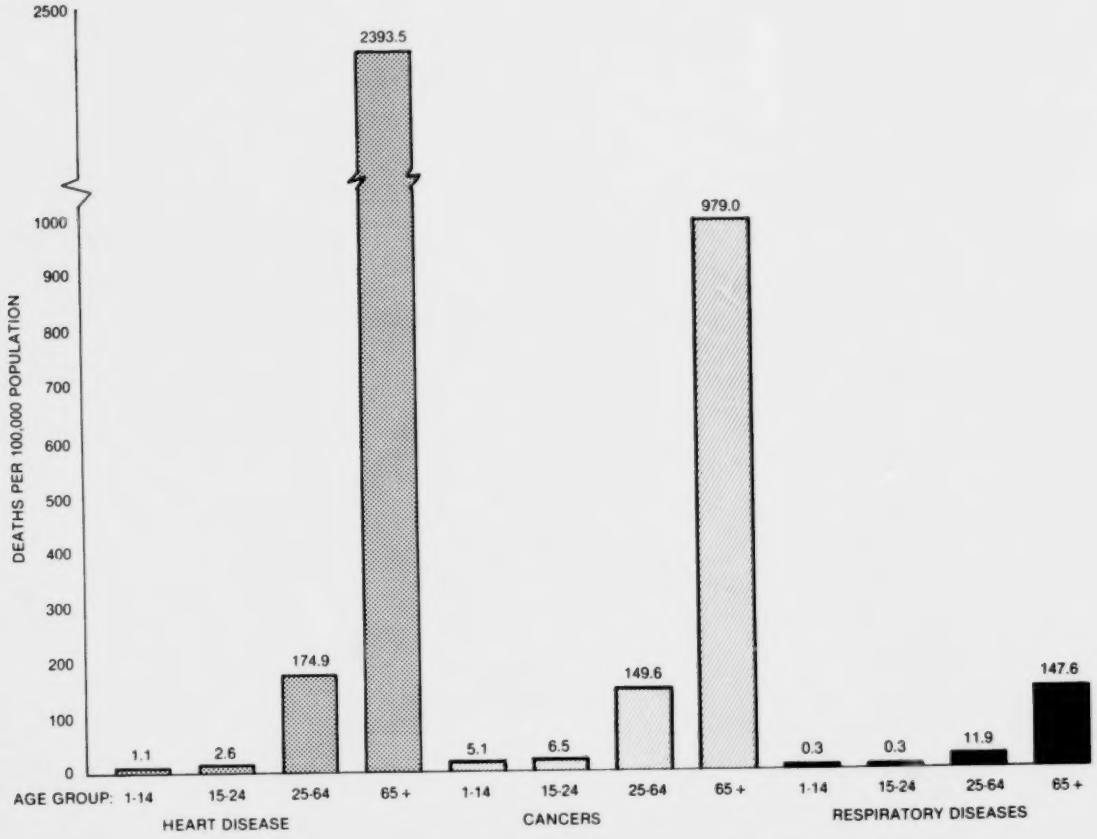


Adapted from: Environmental Quality-1980. The Eleventh Annual Report of the Council on Environmental Quality, 1980, pp. 196, 197.

Figure 2. Age-adjusted Death Rates for Selected Cancers, United States, 1930-1977

With about two out of every three deaths attributable to cancer or heart or lung disease, these three diseases are dominant factors in American public health. Both research and clinical evidence link their occurrence with deleterious factors in the environment.

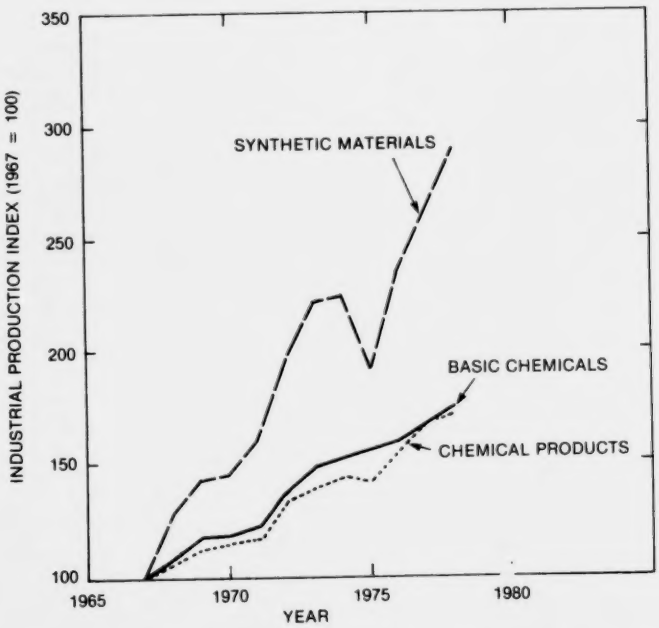
Among persons aged 65 and older, cancer and heart and lung diseases are three of the four leading causes of death (Figure 3). That the prevalence of these diseases and mortality increase with age may indicate the additive and possibly synergistic effects of lifestyle factors, such as smoking and exposure to pollutants, over long time periods.



Source: Vital Statistics of the United States, Vol. 2, Mortality. National Center for Health Statistics. (Published annually.)

Figure 3. Death Rates for Major Causes of Death, by Selected Age Groups, United States, 1976

Although awareness has increased in recent years, the association of the environment with disease, especially cancer, is not a new phenomenon. As early as 1775, Percival Pott established a link between soot and cancer of the scrotum in chimney sweeps. In the 19th century, the workers in the dye industry were observed to have a high incidence of bladder cancer, which was subsequently associated with the use of benzidine in dye manufacturing. Technological progress of the 20th century has brought a vast new array of chemicals into the environment. Over the past quarter century, production growth rates for basic chemicals, chemical products, and synthetic material industries have been very high (Figure 4).



Adapted from: Environmental Outlook 1980. U.S. Environmental Protection Agency. EPA-600/8-80-003, 1980, p. 611.

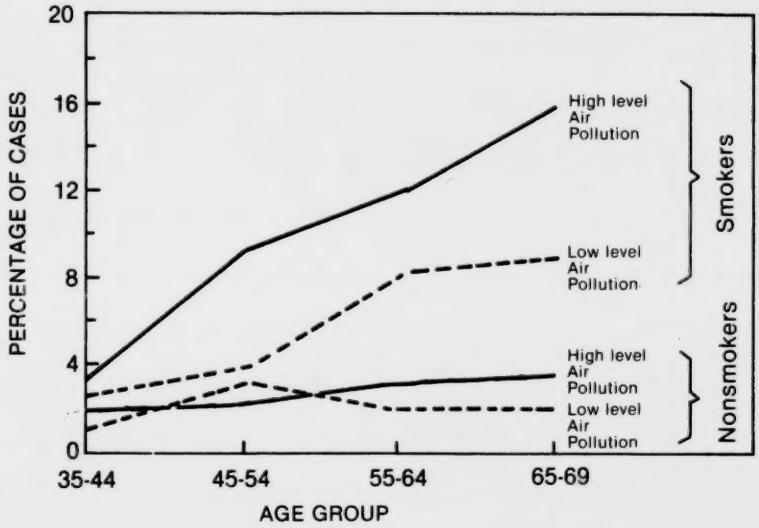
Figure 4. Chemical Industry Production Trends, United States, 1965-1977

About 50,000 synthetic chemicals are currently produced and used in large quantities. Production data from the Environmental Protection Agency's Strategic Environmental Assessment System (SEAS) High Growth Scenario predict continued high growth rates in these industries. While only a small number of these 50,000 synthetic chemicals may be environmentally toxic, the increasing chemical industry production figures may still indicate considerable potential exposure to humans via environmental pathways.

Workers may be exposed to these and other chemicals in the workplace--plastics workers exposed to vinyl chloride are at 200 times greater risk for liver cancer than the general population--and the general population may be exposed to chemicals in the air, water, and food. The National Toxicology Program First Annual Report on Carcinogens, published in 1980, focused on the 26 known carcinogens identified by the International Agency for Research on Cancer, but cautioned that there are more known and suspected carcinogens.

Many risk factors have been found to be associated with heart disease, and some of these may be environmental in origin. While persons who smoke cigarettes are at nearly twice the risk of dying from heart disease as nonsmokers, the risks associated with passive cigarette smoking, an environmental situation over which the individual has little control, are just beginning to be understood. Carbon monoxide, a major component of automobile exhaust, has been associated with the clinical course of heart disease. Some of the heavy metals, especially cadmium, have been found to affect the kidney, and this relates to the development of hypertension, a major risk factor in heart disease. Studies conducted by the National Heart, Lung, and Blood Institute have found geographic patterns of heart disease mortality that might implicate environmental factors.

The respiratory system sustains the most direct insult from pollutants in the ambient air. Asthma, chronic bronchitis, and emphysema are the most common respiratory diseases that have been associated with general air pollution. Figure 5 shows the relationship of air pollution to the prevalence of chronic obstructive pulmonary disease (COPD), which includes emphysema, chronic bronchitis, and fibrotic lung disease, in various age groups in Great Britain. Smoking is shown to be an important variable.



Adapted from: Environmental Quality-1980. The Eleventh Annual Report of the Council on Environmental Quality, 1980, p. 200.

Figure 5. Relationship of Air Pollution Levels to Prevalence of Chronic Obstructive Pulmonary Disease, by Age, Great Britain

Ozone is a major component of smog that is extremely irritating to the respiratory system and can cause increased susceptibility to respiratory infections and pulmonary dysfunction in adults. Nitrogen dioxide is a common component of the ambient air, which at high doses can cause death, usually from pulmonary edema. Exposure to low amounts of nitrogen dioxide over a prolonged period of time can cause loss of pulmonary function. Power plants and factories emit pollutants characterized as sulfur oxides and total suspended particulates.

Adverse health effects have been associated with smaller size particles that can penetrate the upper respiratory system. In addition, it has been estimated that at least half of all occupationally related diseases are respiratory. The coal industry alone spends approximately $1 billion per year in disability payments to persons with black lung disease.

Since cancer and heart and lung disease account for a huge portion of the total morbidity and mortality in the United States, the direct and indirect costs associated with these diseases represent a sizable economic burden.* Table 1 shows the estimated combined costs of these three diseases in 1981 to be $160 billion.**

Table 1. Estimated Costs of Illness by Type of Cost and Disease, United States, 1981 ($ in Billions)

Disease Category	Direct Cost	Indirect Costs		Total All Costs[b]	Percent Distribution All Disease Costs
		Morbidity	Mortality[a]		
Cancer	$11	$ 2	$26	$ 39	8%
Heart	28	17	37	82	17%
Lung	16	18	5	39	8%
	$55	$37	$68	$160	33%

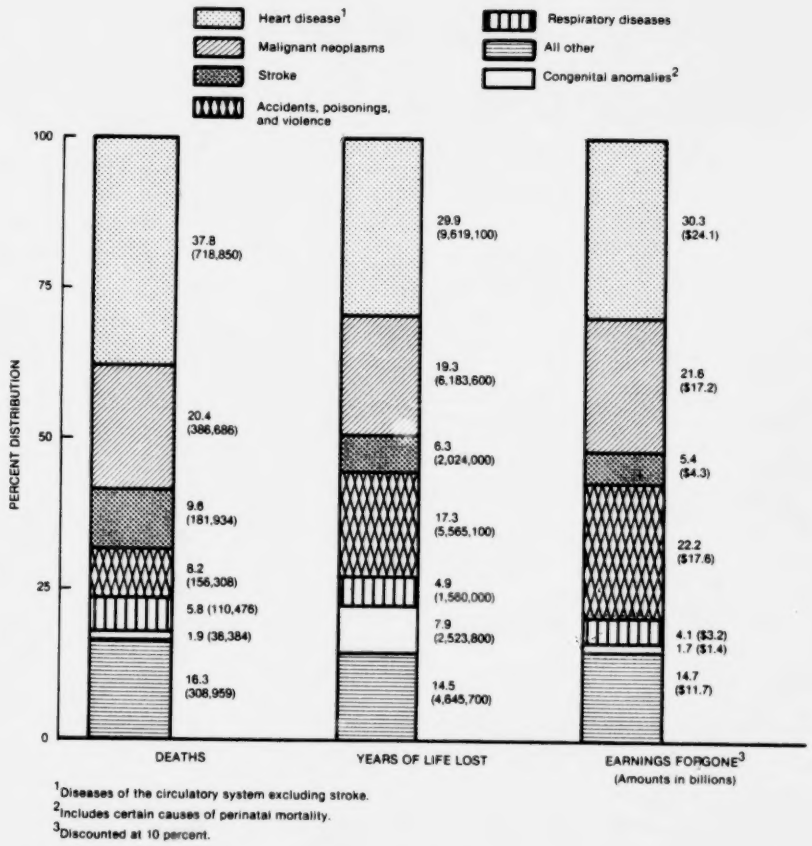
[a] Discounted at 10 percent.
[b] The total of indirect and direct costs of all diseases is approximately $498 billion.

Adapted from: Berk, A., Paringer, L., Mushkin, S. 1978. The economic cost of illness, fiscal 1975. Medical Care 16(9):789; and Freeland, M.S., Schendler, C.E. 1981. National health expenditures: short-term outlook and long-term projections. Health Care Financing Review 2(3):97-138.

* Direct costs include medical care expenditures for prevention, diagnosis, and treatment. Indirect costs are the value of current and future output lost because of reduction or cessation of productive activity due to morbidity, disability, and premature mortality.

** The 1981 estimates are based on HCFA's projection of $247 billion for direct cost of all diseases in 1981 and the assumption that observed relationships between direct and indirect costs and the relationships among disease categories for 1975 have not changed significantly in the intervening years.

Figure 6 shows the relative costs of cancer and heart and lung diseases in terms of years of life lost and earnings forgone, in comparison to number of actual 1977 deaths. The middle bar shows the impact of these diseases on years of lost life, based on current life expectancy rates at each age. Heart disease and cancer still dominate, but because these diseases, along with respiratory diseases, strike at higher frequency rates in older age groups, they account for a smaller proportion of lost years than of deaths.



[1]Diseases of the circulatory system excluding stroke.
[2]Includes certain causes of perinatal mortality.
[3]Discounted at 10 percent.

Source: Health United States, 1980. U. S. Department of Health and Human Services. DHHS Publication No. (PHS)81-1232, 1980, p. 272.

Figure 6. Number and Percent Distribution of Selected Causes of Death, Potential Years of Life Lost, and Earnings Forgone, United States, 1977

The right-hand bar shows the present value of lifetime earnings lost to premature mortality. The percent distribution of lost earnings follows closely that for years of life lost, with a cumulative total for cancer and heart and lung diseases of 56 percent, more than half of the total of all earnings forgone. Thus, the focus of this Task Force on the causal relationship of the environment to cancer and heart and lung disease truly represents a nationwide concern in both health and economic terms.

Although much progress has been made towards linking specific factors in the environment to specific human diseases, definitive evidence to establish causal relationships is currently incomplete. Those causal relationships or inferences cited above are miniscule in number when viewed in light of the many thousands of substances to which we are exposed. Establishment of specific causality is presently hindered by the following factors, among others:

- Cancer and heart and lung disease have multiple causes.
- Humans are not alike in their susceptibility to disease.
- Cancer and heart and lung disease often have a long latency period, and many intervening changes can occur between exposure and the appearance of disease.
- In the "real world," humans are exposed to toxic agents through multiple media, a fact often not considered in laboratory testing of animals.
- Complete data on the identity and amounts of toxic substances in the environment do not exist.
- The mechanisms of toxicity of environmental chemicals are largely unknown.
- Environmental agents may interact to produce additive or synergistic toxic effects.

- Understanding of the mechanisms of mutagenesis and carcinogenesis and the relationship between them is incomplete.
- Epidemiological studies require access to vital individual data that are often not available.

The problem, then, is the existence of both natural and manmade agents in our environment, which have been linked to cancer, lung disease, and possibly heart disease in the human population. The associated costs are great both to our health and our economy. Increased knowledge of the relationships between environmental pollution and human health effects is needed to reduce both the risk and occurrence of these three diseases.

THE TASK FORCE

The Task Force on Environmental Cancer and Heart and Lung Disease was formally established through provisions of the Clean Air Act Amendments of 1977 (Section 402, Public Law 95-95).* Congress directed the Task Force to recommend a comprehensive research program aimed at determining and quantifying the relationship between environmental pollution and these diseases. Towards this mission, the Task Force is to (1) provide strategies for reducing both the risk and incidence of environmentally associated diseases and (2) coordinate research and stimulate cooperation between Task Force member Agencies and other concerned Agencies. The Task Force annually presents recommendations to Congress and the Federal Agencies on environmental disease research and education of the general public and health professionals.

---

* See Appendix A.

The Task Force is currently composed of representatives* from the following eight Agencies:

U.S. Environmental Protection Agency (EPA)

National Cancer Institute (NCI)

National Heart, Lung, and Blood Institute (NHLBI)

National Institute for Occupational Safety and Health (NIOSH)

National Institute of Environmental Health Sciences (NIEHS)

National Center for Health Statistics (NCHS)

Centers for Disease Control (CDC)

Food and Drug Administration (FDA).

EPA chairs the Task Force in its designated appointment by Congress as the lead Agency. Organizational structure of the Task Force is shown in Figure 7.

The Task Force consists of a Plenary Group of Agency directors and their alternates, a Working Group of Agency representatives appointed by the directors, and three specially designated Project Groups of senior scientists, educators, physicians, and research planners from the eight Task Force Agencies.

The Project Groups meet in full and subcommittee sessions to direct activities, to discuss current research findings, to hear special speakers, and to plan and conduct organized workshop sessions to identify areas of research and education needs.

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* Appendix B identifies the members of the Task Force Plenary, Working Group, and Project Groups.

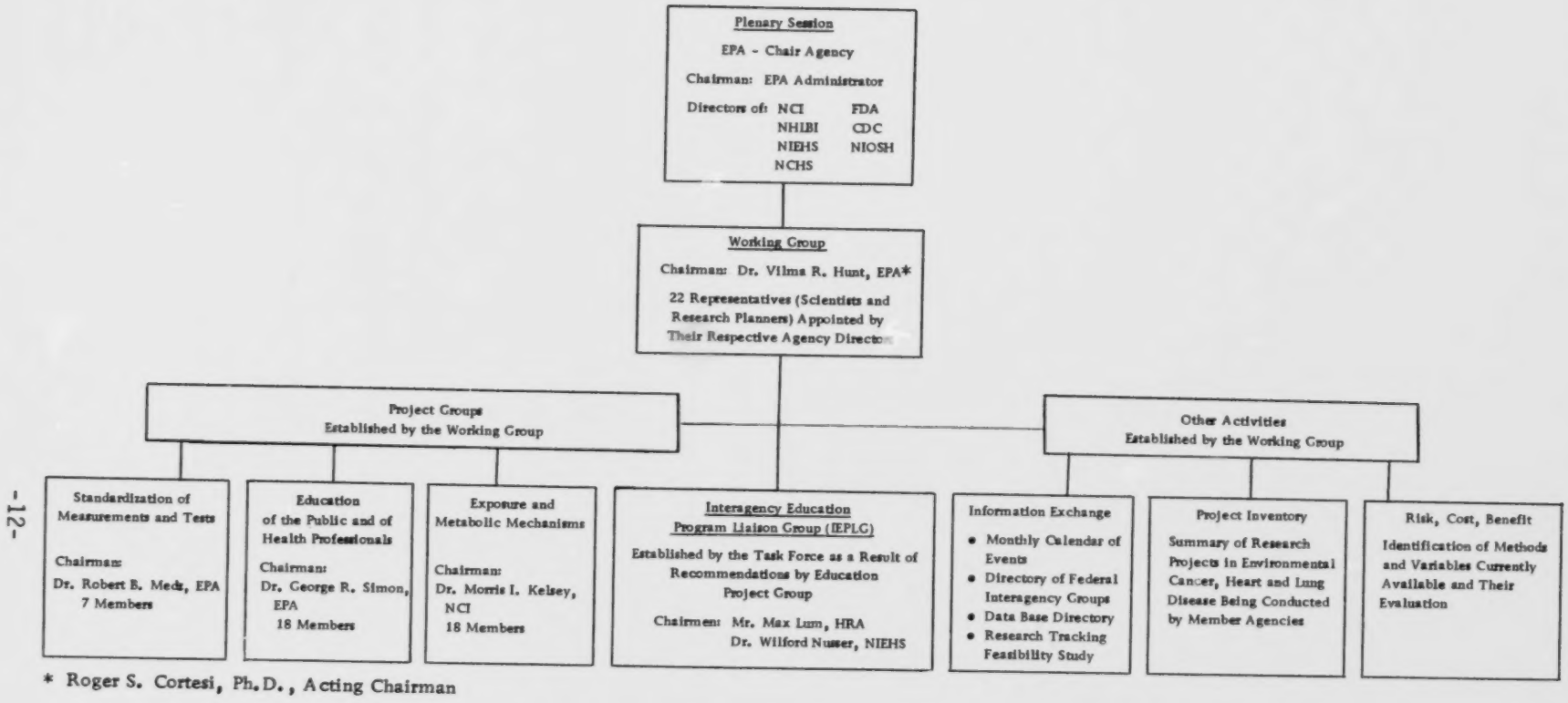
Plenary Session
EPA - Chair Agency
Chairman: EPA Administrator
Directors of: NCI FDA
NHLBI CDC
NIEHS NIOSH
NCHS
Working Group
Chairman: Dr. Vilma R. Hunt, EPA*
22 Representatives (Scientists and Research Planners) Appointed by Their Respective Agency Directors
Project Groups
Established by the Working Group
Other Activities
Established by the Working Group
Standardization of Measurements and Tests
Chairman:
Dr. Robert B. Medz, EPA
7 Members
Education of the Public and of Health Professionals
Chairman:
Dr. George R. Simon, EPA
18 Members
Exposure and Metabolic Mechanisms
Chairman:
Dr. Morris I. Kelsey, NCI
18 Members
Interagency Education Program Liaison Group (IEPLG)
Established by the Task Force as a Result of Recommendations by Education Project Group
Chairmen: Mr. Max Lum, HRA
Dr. Wilford Nusser, NIEHS
Information Exchange
• Monthly Calendar of Events
• Directory of Federal Interagency Groups
• Data Base Directory
• Research Tracking Feasibility Study
Project Inventory
Summary of Research Projects in Environmental Cancer, Heart and Lung Disease Being Conducted by Member Agencies
Risk, Cost, Benefit
Identification of Methods and Variables Currently Available and Their Evaluation
* Roger S. Cortesi, Ph.D., Acting Chairman

Figure 7. Organizational Structure of the Task Force on Environmental Cancer and Heart and Lung Disease

Annually, in April, the Agency directors or their representatives meet in a Plenary Session to review the decisions and recommendations presented by the Working Group, and either approve them for submission to Congress with the Annual Report or return them to the Working Group for further action, as directed.

Progress achieved by the Working and Project Groups is presented in this Fourth Annual Report.

Chapter 2

RECOMMENDATIONS TO CONGRESS

Chapter 2

RECOMMENDATIONS TO CONGRESS

In responding to its mission, the Task Force transmits three recommendations with policy implications in this Fourth Annual Report to Congress. The Task Force Agencies believe that Congress should consider these recommendations because of their importance to research and education efforts in the environmental health field.

These major recommendations to Congress are approved by the Working Group and Plenary members. These recommendations involve supporting the implementation and continuation of the National Death Index, permitting researchers access to Federal data records vital to human epidemiology studies, and developing environmental health programs for clinicians and health professionals.

The Task Force Third Annual Report contained four initial program recommendations in the areas of multimedia pollutant exposure and health effects, transport and fate of pollutants in the biosphere and food chain, biological and chemical measurement methodology and data analysis, and pollutants in groundwater and surface water sources. The current status of these recommendations is described in the second section of this chapter.

FOURTH ANNUAL REPORT RECOMMENDATIONS

> RECOMMENDATION 1. A high priority should be given to the design, implementation, and continued operation of the National Death Index being developed under the auspices of the National Center for Health Statistics.

The National Death Index (NDI) is a central, computerized index of death record information compiled from magnetic tapes submitted to the National

Center for Health Statistics by the state vital statistics offices under contractual arrangements. These tapes (beginning with deaths occurring in 1979) contain a standard set of identifying data for each decedent to be used in searches of the NDI to identify and locate death records filed in the state offices. The NDI will make it possible for investigators conducting statistical and epidemiologic studies to determine whether persons in their studies have died, and if so, it will provide the names of the states where the deaths occurred and the corresponding death certificate numbers and dates of death. The NDI user will then be able to make the necessary arrangements with the appropriate state offices for the procurement of copies of death certificates or for specific statistical information such as cause of death.

The NDI will greatly reduce the effort required in state file searches. In the past, investigators conducting such studies have often found it necessary to contact all or most state vital statistics offices, asking each to search its files to see if a death record may have been filed for any individual in the entire study group. This was a very expensive and time-consuming process. Studies of this type are frequently very large, including thousands of subjects, since the risk under investigation is small on a per individual basis. Furthermore, state vital statistics offices cannot always promptly undertake large file searches because of staff limitations. The NDI, to be made operational in the fall of 1981, will include about 94 percent of all deaths occurring in the United States during 1979. For 1980 and subsequent years, virtually 100 percent of all deaths should be included.

RECOMMENDATION 2. Legal impediments to both Federal and non-Federal epidemiology research should be studied further.

The nature of epidemiologic research requires access to individually identifiable data. Currently, most Federal data bases that contain individual data are protected under various invasion-of-privacy statutes. The need to safeguard individual privacy should not be a barrier to needed health research that uses data records solely for research purposes. Procedures need to be examined for gaining access to Federal data banks by legitimate Federal and non-Federal researchers, while at the same time preserving the individual's rights to privacy.

Cooperation among the National Center for Health Statistics, the Health Care Financing Administration, and the Social Security Administration will facilitate access to pertinent data. Federal Agencies, such as the Veterans Administration and the Internal Revenue Service, should also be encouraged to foster an atmosphere of mutual cooperation in this regard. Appropriate mechanisms to protect individual privacy could be instituted to permit use of these data systems in what is essentially retrospective research.

RECOMMENDATION 3. The development of a coordinated environmental health education program for clinicians and health professionals should be fostered.

Basic medical education generally provides insufficient understanding of the role that environmental and occupational factors play in health problems and disease formation. A recent survey of 112 U.S. medical schools by the Association of Teachers of Preventive Medicine indicated that of 92

schools responding, only 50 percent teach some form of occupational health, usually as one part of a preventive (community) medicine course. This lack of awareness and understanding of environment- and work-related factors among health professionals has been identified as a serious deficiency in the prevention of environmental and occupational disease. Since it is apparent that environmental and occupational factors do contribute to disease, physicians and other health professionals need to recognize both environmentally induced diseases and the relative importance of the environment/workplace to the public health. Heart disease, for example, is often attributable to smoking, dietary, and exercise habits; but little attention is paid to the role of ambient carbon monoxide or possible cadmium exposure. Thus, there is a substantial need to improve and expand the primary knowledge of health professionals regarding the environment and human health.

STATUS OF RECOMMENDATIONS OF THE THIRD ANNUAL REPORT

The Task Force's Third Annual Report contained four program recommendations and additional recommendations in the area of environmental health education programs. The program recommendations were the product of a conceptual approach that combined current scientific knowledge with information on Agency planning processes, current research programs, and information on resource use. These recommendations were to be elaborated on and developed further.

One of these, which stated that comprehensive research should be undertaken to identify the major pollutants in groundwater and in surface water, and to study their persistence and transport, and health effects, was addressed during the past year as the subject of a project on the tracking of research. The progress and status of this project are described in Chapter 4.

The other three program recommendations, on multimedia exposure and health effects, on the transport and fate of pollutants in the biosphere, and on biological and chemical measurement methodology and data analysis, were treated in two of the major sessions (Quantification of Exposure and Methods for Monitoring Individual Exposure to Environmental Pollutants) of the January 1981 Workshop sponsored by the Task Force Project Group on Exposure and Metabolic Mechanisms. This Workshop is described in Chapter 3.

In the area of environmental health education, the Task Force has taken steps to implement the intent of its recommendations by the formation of an Interagency Education Program Liaison Group, whose activities to date are described in Chapter 4.

Chapter 3

SUMMARY OF THE WORKSHOP ON EXPOSURE, METABOLISM, AND MECHANISMS OF TOXICITY

Chapter 3

SUMMARY OF THE WORKSHOP ON EXPOSURE, METABOLISM, AND MECHANISMS OF TOXICITY

The determination of research needs and the establishment of priorities can contribute to the optimal use of resources to reduce environmental disease and improve health. The research needs summarized below resulted from a consensus of scientists at the Workshop on Exposure, Metabolism, and Mechanisms of Toxicity, held January 27-30, 1981, in Rockville, Maryland. Invited position papers served as background and resource material for the Working Group and Plenary discussions. The accompanying document, Summary of the Workshop on Exposure to Environmental Agents, Their Metabolism, and Mechanisms of Toxicity: Research Needs, contains the full text and rationale for the identified research needs, along with a full listing of participants, who included Task Force members, Government scientists, and scientists from industry and academia. The research needs are in six major areas: epidemiology, exposure quantification, individual human exposure monitoring, metabolism, in vivo toxicity, and mechanisms of toxicity and carcinogenesis. The Working Group members will consider the following research needs for their relevance to individual Federal Agencies.

I. EXPOSURE-EPIDEMIOLOGY: NOVEL APPROACHES

Epidemiology is the study of disease patterns and variable factors contributing to such patterns as they occur in human populations. In the case of environmentally related cancer and heart and lung disease, these patterns may not manifest themselves until years after primary exposure. In the interim, other predisposing factors, such as genetic traits and personal habits, may

affect the course of the disease. To reconstruct case histories, the epidemiologist must assemble all factors potentially involved from initial exposure through disease diagnosis and treatment. In light of this, epidemiologic research needs for long-term retrospective studies involve the use of historical data records to help characterize selected populations. Some key research needs in exposure-epidemiology include the following:

I-1. More integrated research on cigarette smoking is needed, particularly on the interaction between smoking and exposure to other potentially toxic agents.

I-2. Additional information should be obtained by the Census Bureau to more adequately describe migration patterns for population-based studies.

I-3. The Social Security Administration (SSA) should not require next-of-kin authorization for the release of information from the quarterly earnings reports. It is also recommended that the SSA provide such information as race, sex, and date of birth for persons under study, when these data are not available from other sources.

I-4. There is a need for more personnel trained in the registration and study of populations likely to be exposed to environmental hazards.

II. EXPOSURE QUANTIFICATION

One problem in determining exposure levels and response relationships is that many environmental disease agents do not have just one exposure route or health effect. Exposure to environmental toxins occurs through numerous pathways. To quantify these multimedia environmental exposures, refined methodologies are needed. Therefore, assessment of human exposure to potential environmental toxins requires estimation of the total exposure through both laboratory and natural settings.

The general research needs in multimedia quantification of exposure related to environmental cancer and heart and lung disease are as follows:

II-1. Multidisciplinary team approaches to environmental research are needed because of the multicausal factors recognized in the etiology of disease.

II-2. Given the variability of geochemical environmental exposures, study populations should be selected to assess the influence of this variability on baseline chronic disease (cancer and heart and lung disease) data.

II-3. Because of growing evidence that domestic pets and certain aquatic species that share a specific chemical exposure with humans have a predictable disease response, studies should be planned and conducted to determine the association between levels of exposure with disease states in animals and man. These studies require the calculation of disease frequencies, as well as chemical analyses of appropriate tissue.

II-4. Emphasis should be placed on determining the rates and extent of absorption of chemicals in animals by various routes of exposure, how such variation affects the response of target organs, and what factors control absorption.

II-5. Aquatic species, both fish and invertebrates, should be used as subjects in short- and long-term in vivo and in vitro laboratory tests of exposure to key environmental pollutants to determine their cumulative capacities and biologic response profiles.

II-6. The balance between positive and negative effects of the prevalence of inorganic cations and anions should be assessed, and the extent of adverse effects (cancer and heart disease) evaluated in terms of prevailing concentrations in the geochemical environment.

II-7. Functions of the personnel of certain regulatory Agencies, such as the Department of Agriculture, should be expanded to link monitoring of disease in farm animals with detection of environmental contaminants to investigate etiologic states relevant to human cancer.

II-8. Because people receive exposures as an integrated stress by inhalation, absorption through the skin, or ingestion via water and diet, such exposures should be defined and quantified to arrive at a total exposure estimate. Animal experiments should be designed to provide an assessment of the various exposure situations that approximate or parallel similar exposures in the human population.

III. MONITORING INDIVIDUAL HUMAN EXPOSURE

Pollutants enter the human environment in numerous ways and in various forms. Monitoring provides measurements of ambient air pollutants, traditionally through fixed-station sources. Because of the various paths and forms that pollutants take, stationary monitoring may not provide an adequate estimate of human exposure. Rather, the use of personal monitoring devices and the development of noninvasive sampling techniques are considered to be much better methods for accurately assessing human exposure. Further progress in developing analytical techniques, especially regarding chemicals in food, is a recognized need.

The following research needs in human exposure monitoring were identified:

III-1. Monitoring direct human exposure is more valuable than monitoring at fixed outdoor stations. At a minimum, the following four types of programs should be considered:

- Total exposure studies of all important pathways (i.e., air, food, water, skin absorption) and all important environments (work, home, commuting, etc.; 24-hour exposure)

- Combined exposure/dose studies--direct measurement of exposure in air, food, and water concurrently with that of contaminant levels in blood, breath, urine, and hair

- "Baseline" monitoring to establish baselines of "healthy" environments against which to compare results of monitoring "unhealthy" areas (toxic dumps, etc.)

- Monitoring in support of epidemiology--relating measurements of individual exposure to individual health effects.

III-2. Despite recent encouraging progress, further advances in sampling and analytical techniques are urgently required to allow estimation of human exposure and dose for hundreds of chemicals. These advances are needed along three broad fronts:

- Sampling techniques--developing personal air quality monitors, food sampling, and contamination-free blood sampling

- Analytical techniques--developing ways to analyze chemicals in food, particulates in air, and volatile organics in the body

- Microanalytical techniques--developing methods for using very small samples and minimizing invasive collection procedures.

III-3. A strong quality assurance program should be initiated for all Government-sponsored collection of environmental data. Results of quality assurance programs should be reported as an integral part of the exposure data. The program should include minimum requirements for blind, duplicate, and control samples, traceability to standards set by the National Bureau of Standards (NBS), etc. Standards for many substances are not available and need to be developed by NBS.

IV. METABOLISM

To improve strategies for assessing environmental cancer and heart and lung disease, scientists and Congress should recognize the general nature of the diseases and the limitations of the various research approaches. Even under the best of conditions, epidemiologic studies by themselves will not

provide all the information needed to discover the environmental etiology of cancer and chronic heart and lung diseases. The epidemiologic approach has been most successful in identifying human carcinogens when the type of cancer or disease produced is one that occurs only rarely in humans. It is, therefore, valuable to recognize the role of metabolism in determining individual sensitivity to toxic agents, since not every toxicant affects every individual in the same way. The mechanisms of toxicity in relation to interacting environmental and genetic factors need to be studied.

The identified research needs in metabolism are as follows:

IV-1. Efforts should be made to determine whether manifestation of environment-related disease may be associated with unusual physiologic or biochemical differences in individuals, including studies on the pharmacodynamics and pharmacokinetics of the suspected toxicant, hypersensitivity reactions, and abnormal cellular biology, and whether observed abnormalities are genetic or environmental in origin.

IV-2. Research should be supported to determine ways in which genetic traits and environmental factors can modify the toxicity of environmental chemicals in animals, since toxicities are mediated by the parent compound or one of its metabolites.

IV-3. The pattern and kinetics of metabolism in animals may change with age of the animal, dose of the substance, season of the year, presence of other substances in the environment, or multiple dosing; therefore, research on the toxicity of environmental chemicals should be accompanied by studies on the disposition of the chemical and its metabolites in the same animal cohort over a range of doses and other variable influencing factors.

IV-4. As a further aid to determining whether a toxicologic event is caused by the parent compound or a metabolite, it is recommended that toxicologic studies be performed in at least two different species or, preferably, in two different strains of the same species that metabolize the compound in markedly different ways.

IV-5. Interdisciplinary research is needed in which acute structural damage (e.g., hepatitis, nephropathy) is correlated simultaneously with the covalent bonding of the chemical or metabolite and the pattern of total metabolites. Research is essential correlating toxic effects with pharmacogenetic differences in metabolism and effects of various diets or of pretreatments that alter metabolism in the same animal cohort.

IV-6. Research is needed to test the hypothesis that acute changes in the intracellular concentration of ionized calcium constitute the final common pathway mediating acute lethal injury from a variety of toxicants, including chemically reactive compounds in the environment, plasma membrane toxins, and anoxia. Documentation of the validity of the hypothesis would then focus the search for the critical target sites responsible for acute lethal injury on those organelles controlling intracellular calcium fluxes. This research could provide exciting new leads into possible treatment of environmentally induced toxicity after the injury.

IV-7. The principles of pharmacokinetics should be incorporated in the design of toxicologic tests to make the tests more economically efficient and the interpretation and extrapolation of the results less equivocal.

IV-8. Research is needed to obtain information on metabolic pathways and the kinetic characteristics of "drug metabolizing" enzymes from in vitro systems to determine the validity of the hypothesis that such information can be used in pharmacokinetic models to predict kinetics of disposition of specific substances in intact animals and humans.

IV-9. To identify the structure-activity relationships and kinetic properties of the various enzymes that metabolize carcinogenic substances and their metabolites in various species and strains of animals, the enzymes need to be isolated from tissues of animals and humans and suitable monoclonal antibodies against them need to be developed.

IV-10. It is recommended that studies of the metabolism of compounds be performed with human tissues to preclude the possibility that unique metabolites are not formed either in humans or in the animal model. In addition, studies of the metabolism of the substance should be carried out in individuals and other living organisms shown to be exposed to the chemical either during production of the chemical or during its field trials.

IV-11. Research is needed to develop mathematical models of carcinogenesis based on the incorporation of more biological information, including pharmacokinetic information and temporal aspects of such relevant information as formation and persistence of DNA adducts and the kinetics of promotion of carcinogenesis in various species. Validation of these mathematical models of carcinogenesis for extrapolation to humans is particularly needed.

IV-12. Research is also needed to evaluate physical-organic and molecular orbital properties of chemically reactive metabolites that might be useful in predicting relative rates in combination with various nucleophiles, including protein and DNA.

IV-13. Research will continue to be needed to identify relevant receptor sites that are involved in the manifestation of cardiovascular and pulmonary diseases and to assess individual and interspecies differences in their specificity, tissue localization, and kinetic properties.

IV-14. The validity and feasibility of using theoretical and quantum chemical predictions of interactions between chemicals and receptor sites should be established. Because quantum chemical calculations currently require large capacity computers, it may be necessary to restrict such programs to a relatively few centers until the costs of computers decline.

V. IN VIVO TOXICITY

The past decade has seen an extensive program of testing chemicals for toxic effects, including the ability to induce cancer and to damage the heart and lungs. Existing legislation, such as the Toxic Substances

Control Act (TSCA), ensures that laboratory testing of chemicals for toxic effects will continue, but this testing program alone is not the solution to the problem of preventing ill health in human populations. Research is needed to develop improved testing systems to better understand the toxic effects seen in laboratory experiments and their relevance to human health. The following areas are considered to be of immediate and fundamental importance to prevention of ill health.

In the area of teratology, the following research needs have been identified:

V-1. A rapid and inexpensive validated method should be developed to detect substances uniquely hazardous to the conceptus. This is particularly important, since many human congenital malformations may be due to environmental agents, whereas others are due to heredity factors.

V-2. Comparative metabolism and pharmacokinetic studies correlated with teratogenic endpoints are required to enhance interspecies extrapolations, which are useful in extrapolating observations in animal models to humans.

V-3. Validated methods are needed to detect physiologic impairments caused by teratogens, rather than morphologic effects, which are now being studied.

V-4. Methods are needed to detect additive or synergistic effects of various factors, since this depicts the actual situation in humans more accurately than exposure to a single factor.

In the area of respiratory tract studies, the following research needs have been identified:

V-5. Greater emphasis should be placed on studies of the upper respiratory tract (i.e., nasopharyngeal) by physiological, morphological, and other techniques.

V-6. More attention should be given to the study of the physical form in which the toxic agent may be inhaled by people (vapor, aerosol, particulates, or vapor absorbed on particulates). This often determines the sites of major impact within the respiratory system.

V-7. Progression to and regression from various intermediate stages or endpoints in pulmonary and upper airway pathology should be studied further, in a manner analogous to the approach now used to study liver pathology.

V-8. Studies designed to understand the mechanism by which a particular pathologic process (e.g., squamous metaplasia) develops in man and animals should aid in assessing the risk to man.

General issues of concern for in vivo toxicity research include the following:

V-9. There should be an emphasis on the rational exploration of toxicologic interactions based on increasing knowledge of the metabolism and mechanisms of action of individual toxicants. Particular attention should be addressed to combinations of agents that may interact in ways that can lead to synergistic toxicities or possibly to entirely unexpected phenomena.

V-10. Techniques are needed to evaluate the hazards of biological agents used in pest control or as agents for decontamination of oil spills and waste dumps. Since it is expected that use of such agents will increase, health hazards of concern include infectivity to nontarget organisms, potential genetic changes to humans, and immune-mediated and pulmonary disease. A research resource should also be established to monitor populations at risk of exposure to these agents.

VI. MECHANISMS OF TOXICITY AND CARCINOGENICITY

The ability of many environmental pollutants to damage the genetic material of humans and animals is important because genetic damage, unless perfectly repaired, will almost certainly cause mutations. A close relationship

exists between mutagenesis (the induction of mutations) and carcinogenesis (the induction of cancer). Thus, agents in the environment that can lead to genetic damage have a very high probability of being carcinogenic. It is possible that these agents may also initiate cellular processes that lead to other chronic diseases, such as atherosclerosis and lung disease.

The understanding of carcinogenesis requires a much more complete understanding of the myriad processes that begin immediately after genetic damage. To understand the sequence of events that leads to cancer requires an understanding of the processes following genetic damage. A great need exists to identify how normal cell replication occurs and how repair processes modify genetic damage. If genetic damage is duplicated, changes are encoded and then expressed as a mutation that may be permanently encoded. Environmental toxins may promote these mutant cells as cancer. Knowledge of the fundamental mechanisms in normal and diseased cellular processes will be gained through support of the following basic biologic research needs:

VI-1. Studies are needed on how initiators initiate and promoters promote carcinogenesis and how inherent mechanisms permit undamaged genetic material to replicate many times without error. It is also important to understand those processes that cause mutations and other forms of cell injury by mechanisms that do not involve direct damage in the genetic material.

VI-2. Research is needed on the basic mechanisms of mutagenesis--mutations that arise spontaneously, as well as those that are caused by environmental pollutants. Such information is necessary for rational approaches to risk assessment of agents in our environment that damage cellular DNA.

VI-3. To detect and/or eliminate mutagens, methods should be developed to quantify in vivo somatic mutation rates in experimental animals and eventually humans. These approaches can be used to explore relations among mutation rate, retrospective cancer incidence, and prospective cancer risks in humans who either belong to families with diverse risks of cancer or reside in environments that confer different cancer risks.

VI-4. Ways should be developed to improve the efficiency of transfer of DNA and of chromatin into cells of humans and other mammals. These techniques will be used to develop recombinant DNA clones that will contain genes responsible for traits associated with malignant transformation of normal cells. To study these properties, additional research should be done with a larger variety of recipient cells to identify those human cell types that can be used as DNA and chromatin recipients in gene transfer experiments. These experimental approaches should reduce the ambiguity in the interpretation of current experiments on expression of cancer cell traits.

VI-5. Sensitive methods should be devised to measure the accumulation of specific DNA adducts and types of DNA damage in tissues of animals exposed to graded amounts of known carcinogens. The goal of these studies would be to determine if certain specific adducts correlate with cytotoxic, mutagenic, and carcinogenic changes, and simultaneous measurement of DNA damage resulting from other than stable adducts should be quantified and correlated with biological changes.

VI-6. Methods of damage accumulation developed in animal models should be applied to studies in human cells to understand why different types of cancer are tissue-specific. Cells from individuals with diseases that involve deficiencies in DNA repair would be particularly useful in these experiments.

VI-7. Investigation is needed of basic molecular mechanisms of tumor promotion, the basis for species and tissue specificity of tumor promoters, and the cellular basis for tumor promotion, especially in the area of cell-to-cell communication. These studies are relevant, since exposure to nonmutagenic but promoting chemicals might be as important in the environmental component of carcinogenesis as are mutagens.

VI-8. Simple screening assays should be developed for tumor promoters that are relevant to human diseases. Such assays will be possible only after information on the basic mechanisms of action of tumor promoters is known.

As evidence of its continued commitment to the advancement of environmental disease research, the Task Force will forward these identified research needs to the appropriate Agencies for review and consideration. The Working Group members will maintain direct liaison with their respective Agencies to ensure that appropriate attention is accorded these research needs and report back to the Task Force on the Agency actions taken.

Chapter 4

ACTIVITIES AND PROGRESS

Chapter 4

ACTIVITIES AND PROGRESS

WORKING GROUP

The success of the Task Force depends, to a great extent, on the ability of the Working Group to (1) plan and act effectively, (2) direct and monitor the ongoing tasks in information exchange, inventory of cancer, heart, and lung disease projects, and risk assessment and cost of disease, (3) synthesize, evaluate, and define recommendations from reports generated by the Education, Standardization, and Exposure/Metabolic Mechanisms Project Groups, and (4) interact with Agency directors of the Plenary to receive consensus approval for recommendations to Congress, Task Force Agencies, and the Task Force. Figure 8 is a graphical representation of these functional interactions.

Representatives from each of the eight Task Force member Agencies constitute the Working Group, whose chairman is appointed by the EPA Administrator. Working Group members direct the progress of the Task Force by overseeing its various activities. They review and evaluate reports of all the Task Force activities and initially develop and/or evaluate the recommendations that are presented to the Plenary for submission to Congress.

Issues come to Working Group attention in the form of suggestions from Working or Project Group members, inquiries from Congressmen, requests from other interagency groups, and as the result of current events. Whatever the source, the Working Group decides on the most appropriate way to

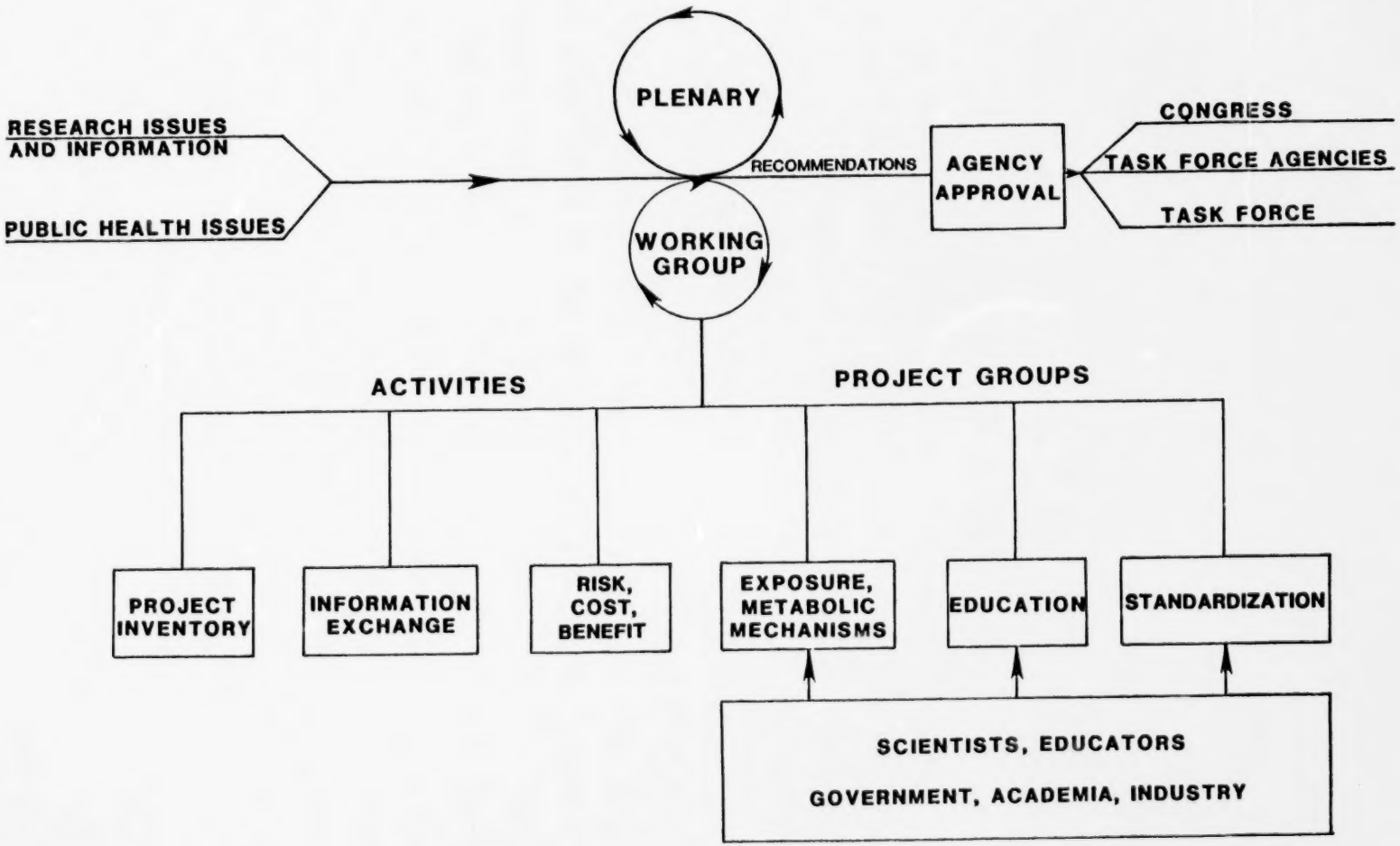

Figure 8. Functional Interactions of the Task Force

deal with the relevant issues. Depending on the nature and complexity of the problem, the Working Group may deal with it in several ways:

- Create a new Project Group
- Make it a general Task Force activity
- Research the issue more thoroughly to allow for an informed decision
- Recommend coordination with other interagency groups currently working on the same question.

The Working Group is responsible for directing all of the Task Force activities and accomplishments discussed in the sections that follow. Some additional specific issues addressed by the Task Force Working Group at their meetings during the last year include the following:

- NCHS pilot studies on disease incidence, prevalence, and cost
- Environmental contaminants or other hazards associated with food
- Development and expansion of the Project Inventory
- Review and preparation of revised recommendations from the Workshop on Exposure, Metabolism, and Mechanisms of Toxicity
- Consideration of radiation as a Task Force concern
- Feasibility of establishing a national resource center for environmental health education.

The specific activities and progress of the Task Force Working Group are summarized in Table 2 and described in detail below.*

* See Appendix C for a complete listing of Task Force publications.

Table 2. Summary of Task Force Activities and Progress, 1980

Project Group on Exposure and Metabolic Mechanisms

- Workshop, January 27-30, 1981
- Publication of Summary of the Workshop on Exposure to Environmental Agents, Their Metabolism, and Mechanisms of Toxicity: Research Needs

Project Group on Education of the Public and of Health Professionals

- Formation of the Interagency Education Program Liaison Group
- Collection of information on environmental health education

Project Group on Standardization of Measurements and Tests

- Feasibility study of quantifying the relationship of quality control to quality of laboratory data
- Survey of federally sponsored chemical measurement programs

Project Inventory

- Review of 10,000 projects; categorization of relevant projects
- Publication of
  - Summary Report
  - A Detailed Profile of Task Force Member Agency Projects in Environmental Cancer and Heart and Lung Disease
  - A Listing of Projects Included in the Project Inventory
  - Abstracts of All Projects Included in the Project Inventory

Information Exchange

- Compilation and monthly dissemination of the Calendar of Events
- Updating and publication of the Directory of Federal Groups Concerned with Environmental Health
- Publication of the Directory of Exposure-Related Data Bases

Research Tracking

- Publication of A Tracking Mechanism for Federal Research: Health Effects of Groundwater Sources of Drinking Water

Interagency Coordination

- Coordination with
  - Interagency Regulatory Liaison Group
  - Committee to Coordinate Environmental and Related Programs
  - Office of Health and Environmental Research (DOE)
  - Interagency Collaborative Group on Environmental Carcinogenesis
- Study of Agency planning mechanisms

Risk Assessment

- Compilation and publication of A Summary of the Legislative Framework for Risk Assessment by Task Force Agencies in the Environmental Health Context.

PROJECT GROUPS

Early in its second year, the Working Group established three interagency subcommittees, known as Project Groups, in the following areas:

- Exposure and Metabolic Mechanisms
- Education of the Public and of Health Professionals
- Standardization of Measurements and Tests.

They were charged with determining (1) the contribution that better knowledge in each area could make to the achievement of Task Force objectives, and (2) the feasibility of undertaking interagency activities to assist in resolving problems in these areas.

The activities of each of these Project Groups during this past year are described below.

Project Group on Exposure and Metabolic Mechanisms

The Project Group on Exposure and Metabolic Mechanisms was established because insufficient information exists on the way toxic substances enter the body and are metabolized. The more that is known about early indicators of disease, the better the Task Force can fulfill its responsibility "to determine and quantify the relationship between environmental pollution and human cancer and heart and lung disease."* Thus, during its meetings throughout the past year, this Project Group of 18 scientists addressed the issues of human exposure to environmental pollutants and their

* Public Law 95-95 (see Appendix A).

metabolism and mechanisms of toxicity. The objective was to identify areas for needed research and propose short- and long-term recommendations to address these needs.

To accomplish this, the Project Group conducted a workshop on January 27-30, 1981, with an interdisciplinary group of scientists from the United States, England, and France as participants. For reference and discussion purposes, these scientists submitted position papers in their respective areas of expertise. The workshop opened with keynote addresses by speakers who presented research, regulatory, and legislative perspectives on the exposure, metabolism, and mechanisms of toxicity of environmental pollutants.

Attending scientists were assigned to one of the six small subgroups on epidemiology, quantification of exposure, individual human exposure monitoring methods, metabolism, in vivo toxicity, and mechanisms of toxicity and carcinogenicity. Participants in each session drafted statements outlining research needs, as well as the accompanying rationales. Results of this notably successful workshop are summarized in Chapter 3.

Project Group on Education of the Public and of Health Professionals

This Project Group was formed for two reasons: (1) the development of an informed citizenry is a useful, long-term strategy for reducing both the costs and risks of environment-related disease, and (2) lack of understanding of environmental factors among health professionals has slowed the prevention and treatment of environment-related disease. This dual focus on health professionals and on the general public has characterized the activities of this Project Group throughout the past year.

Education of Health Professionals

On August 7, 1980, the Task Force recommended formation of an Interagency Education Program Liaison Group (IEPLG) to ensure that member Agencies worked closely together in areas of health education related to occupation- and environment-induced disease and to fulfill the education recommendations that had been set forth in the Third Annual Report of the Task Force.

The Task Force selected a chairman and principal scientist to head the IEPLG and subsequently worked with these individuals in converting the recommendations to specific functions and goals. However, budgetary limitations within the Agencies have delayed complete formation and functioning of the group.

The IEPLG has recommended one primary program initiative for fiscal 1981: a study of the feasibility of a national resource center for environmental and occupational health professional education. Information on the type and content of program materials for professionals in the area of occupational and environmental health is not readily obtainable. Therefore, the major goal of the proposed feasibility study is to identify the sources of these program materials within the Federal and private sectors. It is envisioned that such a resource center would be designed and operated as an information communication conduit, principally for member Agencies of the IEPLG, primary health care practitioners, appropriate national and local professional medical organizations, and health education institutions.

Education of the Public

The general public needs and is entitled to accurate and accessible information on the relationship of the environment and occupation to cancer and heart and lung disease. The Project Group, therefore, has continued to identify and collect information and materials on environmental health education. This data collection reflects a great variety of apparently uncoordinated efforts in public education and awareness of environmental health issues.

The Project Group is preparing a report of current and planned activities and programs on environmentally induced diseases. Such programs are being sponsored by unions, trade associations, public interest groups, Government Agencies, outreach services, and others.

Project Group on Standardization of Measurements and Tests

The Project Group was originally asked, at the February 1979 Plenary Session of the Task Force, to concentrate on the standardization of chemical and physical measurements and tests. Since that time, the focus has narrowed to the development of methods for evaluating and improving the quality and reliability of environmental and occupational monitoring data, with an initial emphasis on chemical measurements and tests.

Feasibility Study

A feasibility study was designed to test the hypothesis that the quality of data produced by individual laboratories is positively related to the share of the analytical workload devoted to analysis of quality control samples. The study is currently based on 1978-1979 data for 12 state laboratories participating in the Epidemiological Studies Program administered by the

EPA Office of Pesticide Programs. If the hypothesis is confirmed with additional data now being collected, it can provide the justification to allocate resources to maintain data quality levels for laboratories operating under budgetary constraints.

Survey of Measurement Programs

A survey of federally sponsored chemical measurement programs has begun with the collection of guidelines and handbooks (principally authored by EPA) and searches of the Federal Register, National Technical Information Service (NTIS), and MEDLINE. This survey will (1) classify data according to sponsoring Agency, chemical group, measurement method, environmental mode, substrate, and measurement purpose and (2) compare results to determine similarities and differences in data quality. Results of comparisons of programs examined in the survey can be used to promote consistency in measurement and testing methods and to develop quality assurance and reporting mechanisms.

SPECIAL ACTIVITIES INITIATED BY THE WORKING GROUP

Activities initiated at the direction of the Working Group include the following:

- Project Inventory
- Information Exchange
- Research Tracking
- Interagency Coordination
- Risk Assessment.

These activities are undertaken to effectively promote Agency cooperation and optimal resource use.

Project Inventory

The Project Inventory is intended to facilitate more effective use of available funds in research and other activities in the area of environment-related disease. It contains all available information on relevant contracts, grants, cooperative agreements, interagency agreements, and inhouse work supported by the eight Task Force member Agencies in fiscal 1980. Relevant projects involved one or more of the following processes: discovering and monitoring pollutants; determining health effects; estimating health risks and economic costs; and developing means to reduce the risk through education, prevention, and control technologies. The projects included in the Inventory were chosen by the Task Force from the perspective of potential uses of the research related to environmental disease. Therefore, for any Agency, the Inventory may include more projects than the number the Agency specifically budgeted for environmental disease-related research.

Inventories had been compiled by the Task Force in past years with only partial success. As an example, last year's effort, entitled the Program Inventory, included input from each Task Force member Agency on estimated fiscal 1980 expenditures for 115 relevant programs. Data were collected through voluntary responses by program managers to questionnaires. The response rate was not 100 percent, and the information was not always detailed enough to be useful.

This year, the Inventory has been carried out at the project level and has been improved and refined to produce a more exhaustive and consistent survey. The focus of the Inventory was shifted from the program to the project level to make use of available computerized data bases

and to use a unit of activity more suitable to the categorization process. Because the unit is smaller, the categorization is clearer. The resulting product is more precise and much more complete. Over 10,000 projects were reviewed, with approximately 4,000 finally included, accounting for about $600 million in research and other activities. The level of funding shown in Table 4 is higher than that reported in previous inventories because of a more thorough survey, the effects of inflation, more member Agencies in the Task Force, and an increase in funding.

The information on projects is grouped into four functional areas:

- Pollutant Identification and Transport
- Human Effects
- Risks and Costs
- Risk Reduction Measures.

Within these four general areas are 13 categories, as listed in Tables 3 and 4 (see Table D-1 in Appendix D for full details). Since some categories are very broad in scope, subcategories were added to increase classification specificity and thus enhance the usefulness of the Inventory (see Table D-2).

Each project was independently characterized for disease endpoint: cancer, heart disease, lung disease, and unspecified. The unspecified classification contains research involving environmentally induced disease that is not specified but may be relevant to cancer or heart or lung disease. If a research project specifically examined an environmental disease other than cancer, heart or lung disease (e.g., environmentally induced neurotoxic effects), it was not included in the Inventory at all. As a result, each

Table 3. FY80 Projects in the Area of Environmental Disease by Task Force Member Agencies

Category	Disease				
	Cancer	Heart	Lung	Unspecified*	Total
1. Identification and Monitoring of Environmental Pollutants	19.8	1.1	15.8	90.4	127.1
2. Identification and Analysis of Sources	9.9	0	34.0	44.6	88.5
3. Environmental Transport and Transformation Analysis	20.0	0	57.3	129.1	206.4
4. Development of Sampling, Analytic, and Monitoring Methods	30.3	0	38.6	180.9	249.8
5. Biological Effects	1,020.0	67.5	176.0	437.0	1,700.5
6. Human Exposure Estimates	6.3	1.7	11.5	31.5	51.0
7. Epidemiology	264.2	39.5	34.4	59.5	397.6
8. Population Risk Assessment	30.1	3.6	8.6	8.1	50.4
9. Costs of Environment-Related Illness	1.3	0	0	2.0	3.3
10. Costs of Control and Prevention	2.3	0.8	16.8	14.9	34.8
11. Education of Public and of Health Professionals	167.1	15.4	11.3	124.9	318.7
12. Preventive Health	242.5	34.4	21.6	18.8	317.3
13. Pollutant Control Measures	17.1	0	27.2	260.8	305.1
Total	1,830.9	164.0	453.1	1,402.5	3,850.5

* Research involving environmentally induced disease that is not specified but may be relevant to cancer and heart and lung disease.

Table 4. Estimated FY80 Expenditures in the Area of Environmental Disease by Task Force Member Agencies (Funding in Thousands of Dollars)

Category	Disease				
	Cancer	Heart	Lung	Unspecified*	Total
1. Identification and Monitoring of Environmental Pollutants	4,628	124	1,706	14,829	21,287
2. Identification and Analysis of Sources	1,196	4	7,081	6,741	15,022
3. Environmental Transport and Transformation Analysis	2,976	0	9,706	15,516	28,198
4. Development of Sampling, Analytic, and Monitoring Methods	3,256	0	5,440	20,598	29,294
5. Biological Effects	153,627	7,371	15,733	50,019	226,750
6. Human Exposure Estimates	2,289	175	791	7,583	10,838
7. Epidemiology	47,113	9,484	5,671	8,247	70,515
8. Population Risk Assessment	5,904	380	184	1,259	7,727
9. Costs of Environment-Related Illness	437	0	0	271	708
10. Costs of Control and Prevention	1,213	384	3,975	4,496	10,068
11. Education of Public and of Health Professionals	27,250	9,025	2,429	28,106	66,810
12. Preventive Health	38,049	16,742	1,414	3,195	59,400
13. Pollutant Control Measures	1,990	0	6,749	53,738	62,477
Total	289,928	43,689	60,879	214,598	609,094

* Research involving environmentally induced disease that is not specified but may be relevant to cancer and heart and lung disease.

project has been classified into a functional group, category and subcategory, as well as disease endpoint.

Project classifications were frequently split among two or more categories or disease endpoints, or only portions of projects were relevant to the Task Force. The number of projects presented in the Inventory are in decimal form to reflect these divisions. In those cases where projects were divided, only the appropriate fraction of the funding was applied to a particular classification.

Data were primarily collected from computerized data bases, supplemented by Agency annual reports, personal requests and interviews, and manual searches of files.

The final publications of this Inventory are:

- Summary Report of the Project Inventory
- A Detailed Profile of Task Force Member Agency Projects in Environmental Cancer and Heart and Lung Disease
- A Listing of Projects Included in the Project Inventory
- Abstracts of All Projects Included in the Project Inventory.

The Summary Report provides details on the methodology and sources of information used in the Project Inventory and contains two sets of matrices: the first tallies the number of projects (see Table 3); the second presents the estimated funding levels for each group of projects (see Table 4). There are nine matrices in each set: one for each of the eight Task Force Agencies,

and one for all Agencies combined (Tables 3 and 4). The Task Force anticipates wide distribution of this summary document.

A Detailed Profile is a breakdown within each category and disease of the number of projects and estimated dollars expended by each division in each Agency. The Listing of Projects includes all relevant research projects and contains information on project number, project title, categorization, fiscal 1980 funding level, contact person, and information source. The information is organized in two ways: (1) by category and disease endpoint, and (2) by division within the Agency. This approach presents the information in the two ways most likely to be needed by the user. Because of their considerable length (400 pages), only moderate distribution is planned for these two reports; they will also be made available to the National Technical Information Service for distribution. The fourth document, Abstracts of All Projects, will be available only for limited distribution (and through NTIS). This document is organized by project number (coded by Agency) and includes abstracts, work scopes, or task descriptions of each project.

This year's Project Inventory provides a comprehensive survey of fiscal 1980 efforts by Task Force member Agencies in the area of environment-related disease. By identifying possible gaps and overlaps in current member Agency programs, the Project Inventory can help improve effectiveness of Federal research efforts. Plans have been made to use the Inventory in the coming year (see Chapter 5). To further assure effective use of the Project Inventory and to assist in improvement of Agency planning processes, Project Inventory reports will be delivered to all Agency planning offices with suggestions for its use.

Information Exchange

The Task Force supports increased coordination of research and cooperation between EPA and Department of Health and Human Services (DHHS) Agencies. In addition to the specific information exchange activities listed below, the Task Force routinely requests and receives documents from Federal interagency groups, special study groups, and Agencies reporting on issues relevant to Task Force concerns. These documents are reviewed and pertinent findings reported to the Working Group.

Calendar of Events

The Calendar of Events, published monthly, contains a list of upcoming meetings, symposia, conferences, seminars, courses, and workshops in environmental health. Its purpose is to promote efficient information exchange among the Federal and non-Federal scientific communities by publicizing meetings. More than 1,000 persons now receive the Calendar each month, including professionals from Federal and state Governments, academia, private industry, and libraries.

Each month over 250 journals, newsletters, and brochures at the Public Health Service, FDA, and NIOSH libraries are reviewed to identify items for inclusion. The Calendar lists all available information, including the title, date, location, sponsor of each meeting, and the fees.

Directory of Federal Interagency Groups

The Task Force is continuing its survey to identify groups and information resources helpful in the analysis of Federal research and planning activities that pertain to environment-caused disease. This survey is being

used to update and expand the annual Task Force publication, Directory of Federal Interagency Groups Concerned with Environmental Health.

The Directory contains a listing of Federal interagency committees that have responsibility for and interests in areas related to the Task Force mission. Each listing contains the roster of members and their Agencies, the authorizing charter, activities and accomplishments, publications, meeting schedule, and subgroups. Chairmen are identified, and a telephone number for each member is included. Over 600 copies of last year's Directory (second edition) were mailed to interested individuals in Federal Agencies, Congress, foreign governments, private industry, and academia. This year, the Task Force is compiling and including an international supplement to the third edition of the Directory. Because of changes in the Federal Government, many of the organizations listed in the Directory are in a state of uncertainty, and therefore, the publication of the Directory may be delayed.

Data Base Directory

The Directory of Exposure-Related Data Bases was requested by the Project Group on Exposure and Metabolic Mechanisms to provide information on primary resources of data concerning human exposure to chemical pollutants. It is designed as a simple-to-use referral system for highly specialized data bases. It includes descriptions of the purpose, scope (including types of pollutants, geographic location, and groups exposed), quality of data, format, and accessibility of each data base. By directing users to the data base appropriate to their topic, this Directory can save valuable time and money.

Research Tracking

The Task Force initiated a research tracking study in an attempt to chart the steps that a recommendation for research undergoes from conception through implementation. The Task Force realized that tracking translation of congressional research recommendations into Agency research plans and grants, and ultimately into research results, could help the Task Force produce useful and effective recommendations.

To do this, the Task Force Working Group initiated a tracking of research in the area of groundwater quality, starting with the recommendations made in the past several years by Government study groups and legislation and then following subsequent plans, projects, and results. Groundwater was specifically chosen for examination because the human health effects of polluted groundwater are a matter of Task Force concern, as reflected in one recommendation presented in the Third Annual Report. The report is an attempt to provide the Task Force with an analysis of how Government responds to research recommendations. The results are intended to provide research planners with suggestions and ideas for more effective tracking of research projects and reporting of results and products. The Working Group has determined that work in this area should continue, as discussed in Chapter 5.

Interagency Coordination

In the past year, significant time and effort have been devoted to developing or increasing interagency coordination. These efforts are described below.

Interagency Groups

The Task Force has, since its inception, maintained informal contact with other groups having similar missions. This year Working Group members reviewed activities of other groups to determine whether increased or formal coordination would be beneficial and decided to implement the following actions:

- Strengtnen coordination with the Interagency Regulatory Liaison Group
- Formalize coordination with the Committee to Coordinate Environmental and Related Programs
- Establish coordination with the U.S. Department of Energy's Office of Health and Environmental Research
- Formalize coordination with the Interagency Collaborative Group on Environmental Carcinogenesis.

Like the Task Force, each of these interagency groups has an interest in, and some responsibility for, matters pertaining to various aspects of environmental disease. Strengthening the ties among them enhances exchange of information and lessens the possibility of costly overlaps in effort.

Agency Planning

During discussion of methods to better coordinate research among the various Federal Agencies, the Working Group suggested examination of Agency planning mechanisms. The resulting study revealed that most research plans are developed through already existing mechanisms such as the following:

- Established proposals and review systems
- Scientist-to-scientist contacts
- Advisory panels specifically set up for research planning.

More important than the specific similarities or differences among these mechanisms is the fact that Agency planning mechanisms are already well determined and not likely to be restructured from outside. Thus, Working Group discussion of this report focused on the best and most realistic ways of influencing Agency research planning. They directed that the Project Inventory report, the Fourth Annual Report to Congress, and other documents be sent to Agency planners for their review and consideration.

Radiation

In response to inquiries from the House Subcommittee on Health and the Environment, the Working Group considered expanding the scope of the Task Force to include the issues of radiation. They reviewed existing committee efforts and reports on both ionizing and nonionizing radiation. The Interagency Radiation Research Committee (IRRC), which includes 14 Federal Agencies, was established to coordinate various Federal projects in ionizing radiation research and provide an information base for the development of appropriate exposure standards. The Subcommittee to Coordinate Radiation Activities (SCRA), as part of the DHHS Committee to Coordinate Environmental and Related Programs, is responsible for identifying program gaps, especially those related to radiation protection issues, and functioning as a coordinator for DHHS radiation-related programs. Because these committees promote research coordination, the Task Force concluded that the most effective plan would be to establish formal contact with these groups (IRRC and SCRA/CCERP), rather than address radiation health effects issues on its own.

In considering the issue of nonionizing radiation, a report presented to the Working Group indicated that there is no substantive evidence linking nonionizing radiation (such as microwaves) to cancer, heart disease, or lung disease. Thus, nonionizing radiation is not an appropriate subject for further Task Force study.

Nutrition

The issue of nutrition initially came to the attention of the Working Group as a result of congressional inquiry. Information acquired from a variety of studies indicates that environmental contaminants in the food chain present a serious health hazard of national importance.

A report by the Office of Technology Assessment in 1979 documents the problem of natural and manmade toxicants in the food chain. The Task Force has chosen to concentrate its efforts in nutritional issues along these lines, emphasizing those nutritional problems that are not under the individual consumer's control. In addition, the Task Force intends to focus on nutrient substances, such as food additives, in terms of their properties as disease promoters or inhibitors. Members of the Working Group believe that focusing on these particular issues provides the most effective link to the Task Force charter.

Cost of Environment-Related Disease

The Program Inventory of 1980 identified one ongoing study on costs of environment-related disease: a congressionally mandated study sponsored by NCHS and conducted by the National Academy of Sciences/Institute of

Medicine (NAS/IOM). The initial effort consisted of development of a plan for an ongoing study of the costs of environment-related health effects. That effort, begun in the fall of 1979, culminated in an IOM report published in January 1981. This report is now being examined and analyzed within DHHS. When completed, the DHHS comments and the IOM report will be transmitted formally to the Committee on Human Resources of the Senate and to the Energy and Commerce Committee of the House of Representatives, as required by Public Law 95-623.

Risk Assessment

The Task Force continues to monitor and track activities of Federal Agencies that have responsibilities for risk assessment in environmental health, as well as similar Federal interagency groups and other organizations. The objectives of this continuing liaison are to keep the Task Force informed of risk assessment activities and to summarize this progress in ways useful both to the Task Force Agencies and to Task Force deliberations.

An example of this function is the comparison of legislative mandates under which Federal regulatory Agencies operate when dealing with carcinogens. For this purpose, the Task Force compiled a document entitled, A Summary of the Legislative Framework for Risk Assessment by Task Force Agencies in the Environmental Health Context. This document summarizes the risk assessment-related provisions of the statutes and mandates of Task Force Agencies and includes the following:

- Definitions of risk, either explicit or implicit
- Evidence required to judge risk

- Evidence other than that on risk to human health that should be considered
- Particular health effects that are the focus of the statute
- Particular populations that need to receive attention
- Extent to which risk should be evaluated relative to the costs of risk reduction
- Precedence of statutes
- Interrelationships of statutes in a regulatory perspective
- Judicial constraints imposed on Agencies conducting risk assessments.

In considering the respective technical areas of costs (health and others), risks, and benefits, it has become evident to the Working Group that each has reached the stage where further consideration of these areas should be carried out by a single element of the Task Force; this is discussed in the next chapter.

Chapter 5

CONTINUING ACTIVITIES AND PLANS

Chapter 5

CONTINUING ACTIVITIES AND PLANS

The Task Force Working Group has approved continuation of the following current efforts:

- Project Groups on Exposure and Metabolic Mechanisms, Education, and Standardization
- The Interagency Education Program Liaison Group
- Project Inventory Analysis
- Information Exchange
  - Publication of the monthly Calendar
  - Updated revisions to Directory of Interagency Groups in Environmental Health
- Research Tracking
- Interagency Coordination
- Formation of a Risk/Cost/Benefit Project Group.

Studies and reports developed by these groups and results of specific assignments by the Working Group will continue to address Task Force objectives of (1) increasing coordination and cooperation among the Federal Agencies to "stretch" dwindling research dollars, (2) developing strategies to reduce environmental disease in a cost-effective manner, and (3) providing recommendations to Congress on timely issues of national concern in environmental health.

Objectives, specific activities, and expected outcomes for the ongoing Task Force projects are summarized in Table 5 and briefly described below.

Table 5. Summary of Projected Task Force Activities, 1981

Project Group on Exposure and Metabolic Mechanisms

- Compilation and publication of scientific papers submitted to Workshop
- Presentation of research needs to Agencies

Project Group on Education of the Public and of Health Professionals

- Feasibility study of a national resource center for environmental and occupational health education
- Report on current and planned health educational activities by groups in the private and public sector, academia, and Federal Agencies

Project Group on Standardization of Measurements and Tests

- Publication of report on the feasibility study relating quality control to quality of laboratory data
- Publication of a report on the survey and classification of federally sponsored chemical measurement programs

Project Inventory

- Analysis for gaps and overlaps in research
- Distribution to Agencies for ad hoc use
- Identification of Agency projects correlated to research needs in Workshop Summary Report
- Identification of Agency projects on health professionals and public education

Information Exchange

- Compilation and monthly dissemination of the Calendar of Events
- Revision and updating of the Directory of Federal Interagency Groups in Environmental Health
- Collection and distribution of relevant interagency documents

Research Tracking

- Study of information on resources and time required by alternative courses of future action being considered by the Working Group
- Pursuit of action chosen by the Working Group

Interagency Coordination

- Continued information exchange and liaison with identified groups working on environmental agents and human health effects

Risk/Cost/Benefit Evaluation

- Formation of a Task Force Project Group to study the issues
- Preparation of a report summarizing perceived connections between measured environmental pollution and human health effects.

PROJECT GROUP ON EXPOSURE AND METABOLIC MECHANISMS

This group of research scientists will continue their work under the leadership of Dr. Morris Kelsey of the National Cancer Institute. Specific objectives of the group are as follows:

- Incorporation of final revisions into their document, Summary of the Workshop on Exposure to Environmental Agents, Their Metabolism, and Mechanisms of Toxicity: Research Needs
- Compilation of a proceedings of scientific position papers on which the above report is based
- Close work with the Task Force Working Group members to present the identified research needs in environmental health to appropriate Federal Agencies for their review and consideration.

PROJECT GROUP ON EDUCATION OF THE PUBLIC AND OF HEALTH PROFESSIONALS

The Education Project Group and the Interagency Education Program Liaison Group have identified a pressing need for dissemination of existing available information on environmental health to health professionals and the general public. Although such information exists in a variety of forms (scientific articles, technical reports, and news pamphlets), there is presently no coordinated center where such information is readily available. In light of this, the Education Project Group and the IEPLG have recommended a feasibility study to design a national resource center for environmental and occupational health education. Issues to be addressed include the scope of the center-clearinghouse, software listings, data base organization, user needs, and available services. The Task Force conclusion that health professionals could benefit from a greater understanding of environmental- and occupational-related disease led to development of the

resource center concept as a centralized approach to disseminating health education materials. The establishment of such a resource center would be predicated on the results of the feasibility study and the availability of funds to support such an undertaking.

The Project Group on Education of the Public and of Health Professionals, chaired by Dr. George Simon of the U.S. Environmental Protection Agency, is directing its efforts toward increasing general public awareness of environmental disease relationships. In support of this, a report will be compiled describing current and planned educational activities sponsored by unions, trade associations, academic institutions, health care institutes, public interest groups, and Federal Agencies. Some specific activities include:

- Use of the Project Inventory to collect Agency data on ongoing and planned public environmental health education
- Collection of data from Federal Agencies that have a commitment to education of the public
- Contacting of those private societies, unions, trade associations, and others that are providing public education materials and support
- Development of an overall matrix of current and planned Federal and private environmental health education offerings and materials for the general public
- Publishing of a report that describes these available offerings; updating and maintaining this data source as a Project Group activity.

PROJECT GROUP ON STANDARDIZATION OF MEASUREMENTS AND TESTS

Under the direction of Dr. Robert Medz of the U.S. Environmental Protection Agency, this group of quality control/quality assurance specialists

will (1) continue studying laboratory data quality in relation to control sample analyses, (2) determine how laboratory performance ratings correlate with the percentage of control samples analyzed, and (3) recommend ways in which this information can be used to improve laboratory performance and data quality. A report describing this feasibility study, its results, applications, and suggestions for further work is projected for the fall of 1981.

A survey of federally sponsored chemical measurement programs is in progress. This involves classification by Agency, chemical group, measurement method and purpose, environmental mode, and substrate. These classifications will be assessed in terms of the desired levels of data quality and means of attaining them. A report describing this study will be prepared for the Working Group late in 1981.

PROJECT INVENTORY

The Project Inventory represents a unique compilation of information on the fiscal 1980 environmental health research and other activities of the Task Force Agencies. By classifying each member Agency's research, testing, monitoring, and educational projects according to type of activity and disease endpoint, the Task Force can profile funding trends and the Federal efforts in environment-related disease. The Project Inventory, described previously, is now entering an extensive analysis phase, with the objective of identifying research gaps and overlaps. Final analyses will be prepared and submitted to the Working Group, outlining the major findings and recommendations. A limited update of projects for fiscal 1981 is planned to establish a tracking system of expenditures in environment-related disease. The Inventory will be distributed to the Agencies for their ad hoc use.

Some specific areas where the Project Inventory will be used are:

- A cross analysis of Agency projects in environmental cancer and heart and lung disease with the research needs identified by the Project Group on Exposure and Metabolic Mechanisms
- Identification of current Agency projects in health professional and public education by the Project Group on Education.

The Project Inventory itself can serve as a resource planning tool, allowing Agency staff to view their own programs, as well as those of other Agencies. The anticipated result is a more efficient and coordinated research effort among the member Agencies.

INFORMATION EXCHANGE

Information exchange is one cost-effective mechanism for achieving increased coordination and cooperation among Federal Agencies. Ongoing activities that have been successful in fostering exchange of ideas and information will be continued this year. These include the following:

- The monthly Calendar of Events
- The Directory of Federal Interagency Groups Concerned with Environmental Health
- Summary of reports and recommendations from interagency groups in environmental health and related areas.

As a service to the scientific, industrial, governmental, and academic communities, the Task Force Calendar of Events will continue to be prepared each month. The Calendar encompasses a wide range of information on meetings, conferences, and symposia in the environmental health field. The

Calendar is a useful resource for individuals who wish to keep informed of current and projected meetings on environmental and occupational health topics in the United States and abroad.

The Directory will be revised and updated during the coming year as new information on the roster of members and their Agencies, the authorizing charter, activities and accomplishments, publications, meeting schedules, and subgroup formations becomes available. The Directory is a valuable resource to individuals in Federal Agencies, private industry, and academia.

Another means of maintaining a high level of awareness of related Government activities is the collection of documents from Federal interagency groups and other sources relevant to Task Force concerns. Such reports published during the next year will be reviewed and summarized for presentation to the Working Group. These summary reports provide the Task Force with factual information for specific Task Force subject areas and pertinent highlights of ongoing activities by other interagency groups. In this manner, the Task Force maintains a quick access method for keeping abreast of the wide-ranging reports on environmental health issues.

RESEARCH TRACKING

After a review of the Research Tracking Report on groundwater quality, the Task Force considered several possible courses of future action: a broader study, intensive use of and correlation with the Project Inventory, and an in-depth analysis of the projects used in the pilot study. Information will be developed on the time and resources required for each option, and the Working Group will determine which to pursue.

COORDINATION

The Task Force continues to develop and maintain liaison with those groups that have interest in and responsibility for matters pertaining to environmental agents and human health effects. The following committees have been specifically identified for increased exchange of information. Formal liaison and interaction with the Task Force is underway.

- Interagency Regulatory Liaison Group (IRLG). Members include EPA, FDA, Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), and USDA Food Safety and Quality Service (FSQS). Their mission is to "improve the protection of public health and the environment through sharing of information and developing consistent regulatory policies."

- Committee to Coordinate Environmental and Related Programs (CCERP). Members include DHHS Agencies, DOL, Department of Energy (DOE), Department of Defense (DOD), EPA, National Science Foundation (NSF), Council on Environmental Quality (CEQ), National Oceanic and Atmospheric Administration (NOAA), FSQS, and CPSC. Their interests include environmental mutagenesis, carcinogen safety standards, and toxicology information.

- Interagency Collaborative Group on Environmental Carcinogenesis (ICGEC). Their mission is to maintain "coordination and collaboration" of Federal activities in environmental cancer research.

- Office of Health and Environmental Research (OHER) of the DOE. Their program relates to health effects of energy technologies and resulting environmental pollutants. Major program areas are carcinogenesis, mutagenesis, systems toxicology, and basic biology.

RISK/COST/BENEFIT EVALUATION

The Task Force is interested in the need to understand the effects of environmental pollution in relation to risk assessment. Determination of relative exposure and health risks is a necessary prerequisite for the decision-making process that establishes pollutant standards. The Working Group has

approved the formation of a Project Group to address the risk/cost/benefit issues associated with environmental pollution.

Some members of the Exposure and Metabolic Mechanisms Project Group, along with other Task Force members and Federal experts in this area who will constitute this study group, will prepare a report summarizing what can presently be concluded about the connections between measured environmental pollution and human health effects. The report will address the following:

- Identification of important variables that pertain to measurement of environmentally induced morbidity/mortality
- Identification of current environmental pollution-human health effects models
- Modification, if necessary, of current models to improve their validity
- Identification of circumstances in which risk/cost/benefit analysis should and can be applied.

In combination with this effort, the Task Force will continue to follow the progress of the National Academy of Sciences/Institute of Medicine study on the costs of environment-related disease. The Task Force will also seek out other groups with similar interests in environmental health costs.

Appendix A

PERTINENT SECTION OF PUBLIC LAW 95-95

Appendix A

PERTINENT SECTION OF PUBLIC LAW 95-95

PUBLIC LAW 95-95

Clean Air Act Amendments of 1977

"INTERAGENCY COOPERATION ON PREVENTION OF ENVIRONMENTAL CANCER AND HEART AND LUNG DISEASE

Sec. 402. (a) Not later than three months after the date of enactment of this section, there shall be established a Task Force on Environmental Cancer and Heart and Lung Disease (hereinafter referred to as the 'Task Force'). The Task Force shall include representatives of the Environmental Protection Agency, the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute [for] Occupational Safety and Health, and the National Institute [of] Environmental Health Sciences, and shall be chaired by the Administrator (or his delegate).

(b) The Task Force shall--

(1) recommend a comprehensive research program to determine and quantify the relationship between environmental pollution and human cancer and heart and lung disease;

(2) recommend comprehensive strategies to reduce or eliminate the risks of cancer or such other diseases associated with environmental pollution;

(3) recommend research and such other measures as may be appropriate to prevent or reduce the incidence of environmentally related cancer and heart and lung diseases;

(4) coordinate research by, and stimulate cooperation between, the Environmental Protection Agency, the Department of Health, Education, and Welfare, and such other agencies as may be appropriate to prevent environmentally related cancer and heart and lung diseases; and

(5) report to Congress, not later than one year after the date of enactment of this section and annually thereafter, on the problems and progress in carrying out this section."

Appendix B

MEMBERS OF THE TASK FORCE, WORKING GROUP, AND PROJECT GROUPS

Appendix B

MEMBERS OF THE TASK FORCE, WORKING GROUP, AND PROJECT GROUPS

TASK FORCE PLENARY

EPA	John W. Hernandez, Deputy Administrator	Chairman
	Walter C. Barber, Acting Administrator	Chairman (1/81-5/81)
	Douglas M. Costle, Administrator	Chairman (3/78-1/81)
	Richard M. Dowd, Acting Assistant Administrator for Research and Development	Alternate (12/80-Present)
	Stephen J. Gage, Assistant Administrator for Research and Development	Alternate (3/78-11/80)
	Vilma R. Hunt, Deputy Assistant Administrator, Office of Health Research	Working Group Chairman (11/79-5/81)
	Roger S. Cortesi, Acting Director, Office of Health Research	Acting Working Group Chairman (6/81-Present)
NCI	Vincent T. DeVita, Director	
	Herman F. Kraybill, Scientific Coordinator for Environmental Cancer, Division of Cancer Cause and Prevention	
NHLBI	Robert I. Levy, Director	
	Suzanne S. Hurd, Acting Director, Division of Lung Diseases	(1/81-Present)
	Claude J.M. Lenfant, Director, Division of Lung Diseases	(3/78-1/81)
	Hugh B. Stamper, Division of Lung Diseases, Interstitial Lung Diseases Branch	
	Manning Feinleib, Associate Director for Epidemiology and Biometry, Division of Heart and Vascular Disease	
NIOSH	Ronald F. Coene, Acting Director	(3/81-Present)
	Anthony Robbins, Director	(3/78-3/81)
	Kenneth Bridbord, Director, Office of Extramural Coordination and Special Projects	(2/81-Present)
	Ralph E. Yodaiken, Medical Science Advisor, Office of Extramural Coordination and Special Projects	(3/78-2/81)
NIEHS	David P. Rall, Director	
	Raymond E. Shapiro, Assistant Director for Toxicology Coordination	
CDC	William H. Foege, Director	
	Clark W. Heath, Director, Chronic Disease Division	

TASK FORCE PLENARY (Concluded)

NCHS	Dorothy P. Rice, Director	
	Rosalie A. Dunn, Epidemiology Branch, Office of Statistical Research	
	Sam C. Marcus, Special Assistant to the Director	
FDA	Arthur H. Hayes, Jr., Commissioner	(4/81-Present)
	Jere E. Goyan, Commissioner	(10/79-2/81)

WORKING GROUP

EPA	Vilma R. Hunt, Deputy Assistant Administrator, Office of Health Research	Chairman
	George R. Simon, Science Review Administrator for Health Research, Office of Research and Development	
	Robert B. Medz, Senior Environmental Scientist, Water and Waste Management Division, Office of Monitoring Systems and Quality Assurance	
NCI	Herman F. Kraybill, Scientific Coordinator for Environmental Cancer, Division of Cancer Cause and Prevention	
	Morris I. Kelsey, Assistant to Scientific Coordinator, Division of Cancer Cause and Prevention	
NIEHS	Wilford L. Nusser, Associate Director for Extramural Programs	
	Raymond E. Shapiro, Assistant Director for Toxicology Coordination	
NIOSH	Max Lum, Medical Education Specialist, Division of Medicine, Bureau of Health Professions	
	Howard Sandler, Medical Officer, Office of Extramural Coordination and Special Projects	
	Ralph E. Yodaiken, Medical Science Advisor, Office of Extramural Coordination and Special Projects	(3/78-2/81)
	Kenneth Bridbord, Director, Office of Extramural Coordination and Special Projects	(2/81-Present)
	William A. Felsing, Deputy Director, Office of Extramural Coordination and Special Projects	(3/78-2/81)

WORKING GROUP (Concluded)

NHLBI	Suzanne S. Hurd, Acting Director, Division of Lung Diseases	(1/81-Present)
	Claude J.M. Lenfant, Director, Division of Lung Diseases	(3/78-1/81)
	Hugh B. Stamper, Division of Lung Diseases, Interstitial Lung Diseases Branch	
	Manning Feinleib, Associate Director for Epidemiology and Biometry, Division of Heart and Vascular Diseases	
	A. Richey Sharrett, Medical Officer, Division of Heart and Vascular Diseases, Epidemiology Branch	
CDC	Clark W. Heath, Director, Chronic Disease Division	
	George Hardy, Assistant Director, Chronic Disease Division	
NCHS	Rosalie A. Dunn, Epidemiology Branch, Office of Statistical Research	
	Sam C. Marcus, Special Assistant to the Director	
FDA	Constantine Zervos, Director, Scientific Liaison Staff	
	Lois Ann Beaver, Staff Science Advisor	

PROJECT GROUPS

Education of the Public and of Health Professionals

EPA	George R. Simon, Science Review Administrator for Health Research, Office of Research and Development	Chairman (3/81-Present)
	Karen Morehouse, Program Analyst, Division of Air, Noise, and Radiation, Office of Health Research	
NIOSH	Ralph E. Yodaiken, Medical Science Advisor, Office of Extramural Coordination and Special Projects	Chairman (3/78-2/81)
	Alan D. Stevens, Director, Division of Training and Manpower Development	
	P.G. Rentos, Training Grant Program Officer, Division of Training and Manpower Development	
	Marsha Bernard, Occupational Health Nurse Educator, Division of Training and Manpower Development	

PROJECT GROUPS (Continued)

Education of the Public and of Health Professionals (Concluded)

NCI	Margaret H. Sloan Special Assistant for Liaison Activities, Division of Cancer Control and Rehabilitation	
NIEHS	Wilford L. Nusser, Associate Director for Extramural Programs	
NCHS	Sam C. Marcus, Special Assistant to the Director	
NHLBI	Daniel J. Rubin, Chief, Program Planning and Evaluation Branch, Office of Program Planning and Evaluation Sydney Parker, Psychologist, Division of Lung Diseases, Prevention, Education and Manpower Branch	
DOL	Edward J. Bergin, Program Analyst, Office of the Assistant Secretary for Policy, Evaluation and Research	
OSHA	Earl D. Heath, Director, Office of Training and Education	
ED	Walter J. Bogan, Director, Office of Environmental Education	
HRA	William J. Holland, Deputy Chief, Education Development Branch; Chief, Program Development Section, Division of Associated Health Professions, Bureau of Health Professions Louis Steinberg, Chief, Educational Development Report Section, Educational Development and International Activities Branch, Division of Medicine, Bureau of Health Professions Max Lum, Medical Education Specialist, Division of Medicine, Bureau of Health Professions Nancy J. Story, Program Analyst, Division of Medicine, Bureau of Health Professions	

Standardization of Measurements and Tests

EPA	Robert B. Medz, Senior Environmental Scientist, Water and Waste Management Division, Office of Monitoring Systems and Quality Assurance	Chairman
	Christopher Timm, Director, Quality Assurance Management Staff	

PROJECT GROUPS (Continued)

Standardization of Measurements and Tests (Concluded)

NIAMDD	Cyrus Creveling, Laboratory of Bioorganic Chemistry	
NIOSH	Judd Posner, Robert A. Taft Laboratories	
NIEHS	Phillip Albro, Environmental Chemistry Branch	
CDC	David D. Bayse, Clinical Chemical Division	
FDA	Lois Ann Beaver, Staff Science Advisor	

Exposure and Metabolic Mechanisms

NCI	Morris I. Kelsey, Assistant to Scientific Coordinator, Division of Cancer Cause and Prevention	Chairman
	Herman F. Kraybill, Scientific Coordinator for Environmental Cancer, Division of Cancer Cause and Prevention	
	Elizabeth K. Weisburger, Assistant Director for Chemical Carcinogenesis, Division of Cancer Cause and Prevention	
	Thomas J. Mason, Chief, Population Study Section, Environmental Epidemiology	
FDA	Tim Henry, Staff Science Advisor, Office of Health Affairs	
	Ronald W. Hart, Director, National Center for Toxicological Research	
NIOSH	Richard W. Niemeier, Section Chief, Acute and Subchronic Toxicology, Division of Biomedical and Behavioral Sciences	
	Harry B. Plotnick, Section Chief, Mechanics of Industrial Disease, Division of Biomedical and Behavioral Sciences	
	Pervis C. Major, Chief, Immunology Section, Division of Respiratory Disease Studies	
EPA	Lance Wallace, Environmental Scientist, Office of Monitoring Technology Support	
	Wayne M. Galbraith, Toxicologist, Office of Health Research	

PROJECT GROUPS (Concluded)

Exposure and Metabolic Mechanisms (Concluded)

NIEHS	Larry G. Hart, Assistant to the Director
NCHS	Sam C. Marcus, Special Assistant to the Director
CDC	Jean French, Health Scientist, Chronic Disease Division Clark W. Heath, Director, Chronic Disease Division
NHLBI	James Gillette, Chief, Laboratory of Chemical Pharmacology Daniel J. Rubin, Chief, Program Planning and Evaluation Branch
USDA	John E. Spaulding, Director, Residue Evaluation and Surveillance Division, Food Safety and Quality Service

Appendix C

LIST OF PUBLICATIONS ORIGINATING
FROM THE
TASK FORCE ON ENVIRONMENTAL
CANCER AND HEART AND LUNG DISEASE

Part 1, 1981
Part 2, 1978-1980

Appendix C

LIST OF PUBLICATIONS* ORIGINATING
FROM THE
TASK FORCE ON ENVIRONMENTAL
CANCER AND HEART AND LUNG DISEASE

Part 1, 1981

Summary of the Workshop on Exposure to Environmental Agents, Their Metabolism, and Mechanisms of Toxicity: Research Needs, August 1981

This report presents the full text and rationale of 72 research recommendations developed through a consensus of scientific experts at a Workshop on Exposure, Metabolism, and Mechanisms of Toxicity held in January 1981. In final form, the document represents a compilation of research needs for environmental cancer and heart and lung disease in areas such as epidemiology, exposure quantification and monitoring, metabolism, and disease processes. Both short- and long-term needs are identified in a balanced focus on basic and applied environmental disease research.

Publication of Position Papers from the Workshop on Exposure to Environmental Agents, Their Metabolism, and Mechanisms of Toxicity, In Progress

Papers submitted by a selected team of scientists and utilized as background and reference sources for Workshop discussion are presented in a separate volume reflecting the multidisciplinary approach of the Workshop. A wide range of topics includes: initiation/promotion concepts of carcinogenesis, toxicologic interactions and pathogenesis of lung and heart disease, and total exposure models in animals and humans.

Project Inventory

1. Summary Report of the Project Inventory, August 1981

This document is one of four publications produced through this year's comprehensive survey of fiscal 80 research projects sponsored by Task Force Agencies. The Summary Report outlines and discusses the background of the previous Inventories and summarizes the current methodology used in compiling and categorizing project information. Descriptors, including research

* These publications are available from Ms. Joanna Fringer, GEOMET Technologies, Inc., 1801 Research Blvd., Rockville, Maryland, 20850, 301/424-9133.

category, subcategory, disease endpoint, and Agency division, are utilized in summary matrices which present totals in terms of number of projects and funding levels. This report provides a unique comprehensive picture of Task Force Agency environmental health research efforts.

2. A Detailed Profile of Task Force Member Agency Projects in Environmental Cancer and Heart and Lung Disease, 1981

Presented in this publication is a detailed breakdown of Agency activities and expenditures. The number of projects and dollars expended according to category and disease endpoint are shown for each Agency and division.

3. A Listing of Projects Included in the Project Inventory, 1981

This document lists all relevant research projects and includes information on project number, project title, categorization, funding level, and contact person. The data are organized by subject area and by Agency. Thus, relevant projects can be identified either by subject area or sponsoring Agency.

4. Abstracts of All Projects Included in the Project Inventory, 1981

This limited edition is a compilation of abstracts of the approximately 4,000 projects included in the Project Inventory. The abstracts are arranged in order of project number and contain work scopes or job descriptions of each project.

Directory of Federal Interagency Groups Concerned with Environmental Health

Third Edition: Fall 1981. This edition contains revised listings of the interagency committees included in the 1980 Directory. Each listing includes names of committee representatives, the authorizing charter, relevant publications and accomplishments, and meeting schedule. As a supplement to the third edition, a section on international groups is also included.

A Tracking Mechanism for Federal Research: Health Effects of Groundwater Sources of Drinking Water, 1981

This report delineates the stages that research recommendations undergo from inception through implementation, using groundwater quality as the topic of concern. By tracing the recommendations made in the groundwater area over the past few years, the report follows subsequent plans, research projects, and findings in an attempt to analyze how Government responds to research recommendations.

Directory of Exposure-related Data Bases, 1981

This directory is designed to provide the user with key information on a variety of specialized exposure data bases. A description of the purpose, scope, quality of data, format, and accessibility of each data base is included.

Summary of Reports and Recommendations of Interagency Committees with Relevance to the Task Force, In Progress

This report summarizes the major recommendations of other interagency committees in the area of environmental health. Designed as a resource to facilitate information exchange, the report contains recent developments and findings of various groups in areas as diverse as health effects of coal technologies and environmental contaminants in food.

Feasibility Plan for a Resource Center on Environmental and Occupational Health Professional Education Material, In Progress

This report will consider the issue of establishing a national center for the dissemination of available information on environmental health to both health professionals and the general public. Information will be compiled describing current and planned educational activities in the public sphere, as well as types of materials available in the medical sector.

Feasibility Study on Data Quality, In Progress

The Project Group on Standardization of Measurements and Tests is currently developing a study dealing with quality of data produced by chemical laboratories. As background to the analysis, a compilation and review of chemical measurement programs will be conducted with the results forming the basis of data quality indices.

A Summary of the Legislative Framework for Risk Assessment by Task Force Agencies in the Environmental Health Context, 1981

This document compares the legislative mandates under which Federal regulatory Agencies operate when dealing with carcinogens. The report presents the criteria used in judging risk, defines what constitutes a health risk, and analyzes the role of costs and benefits related to risk reduction vis-a-vis regulation.

Calendar, Monthly Issue

The Calendar is distributed monthly to facilitate information dissemination within a 3-month time frame. The Calendar includes announcements of meetings, conferences, symposia, courses, public hearings and workshops that pertain to environmental pollution and disease.

LIST OF PUBLICATIONS ORIGINATING
FROM THE
TASK FORCE ON ENVIRONMENTAL CANCER
AND HEART AND LUNG DISEASE

Part 2, 1978-1980

First Annual Report to Congress by the Task Force on Environmental Cancer and Heart and Lung Disease, August 7, 1978

In this first report to Congress, the Task Force summarized the problem of environmental cancer and heart and lung diseases as an interagency/interdisciplinary issue that faced the Nation as of 1978. The Task Force subsequently identified six important areas of research in which early interagency cooperation could address these issues. These research areas are: standardization of measurements and tests, exposure and metabolic mechanisms for pollutants, early indicators of disease, risk assessment, education of the public and of health professionals, and strategies to protect public health.

Environmental Pollution and Cancer and Heart and Lung Diseases, Second Annual Report to Congress, August 7, 1979

In the Task Force report to Congress on its second year of work, the following progress was indicated and described. Project Groups were formed on Standardization of Measurements and Tests, Education of the Public and of Health Professionals, and Exposure and Metabolic Mechanisms. Information exchange among member Agencies of the Task Force was considered the primary basis for establishing coordination and development of interagency programs. Funding was identified and classified in each Task Force member Agency. Approximately $270 million was spent in 1978 by the seven Agencies on research and strategy planning addressed to Task Force objectives.

Environmental Cancer and Heart and Lung Disease, Third Annual Report to Congress, August 7, 1980

This document presents the major activities of the Task Force during its third year and describes the initial process for developing specialized recommendations relevant to the Task Force mission. In addition to the expansion of information exchange activities (and the inclusion of FDA as the eighth member), the Task Force continued to increase its efforts in the areas of environmental health education and also risk assessment as enumerated in a separate report comparing the various criteria used by Federal Agencies to regulate carcinogens. An inventory of Agency-funded research at the program level is included for this Third Annual Report.

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* These publications are available from Ms. Joanna Fringer, GEOMET Technologies, Inc., 1801 Research Blvd., Rockville, Maryland, 20850, 301/424-9133.

Report of the Inventory of Federal Research Programs of Relevance to the Task Force, April 1980

This initial inventory is a compilation of research program information from Task Force member Agencies in a common format for 115 research programs. Details pertaining to each research program are given to facilitate general coordination. Summary information on program description, resources applied, person-year effort, objectives and mandated responsibilities, activities, and future research and resource needs is included. The limitations of the inventory are given in Section 2, page 9. This inventory was revised during Fall 1980.

Summary of the Workshop on Environmental Education Needs of Health Professionals, December 1979

Held by the Project Group on Education of the Public and of Health Professionals, this 2-day workshop identified the needs of health professionals in environmental education. To meet these needs, the workshop participants developed action plans that were aimed at increasing health professional capability in effective prevention of environment-related disease. Workshop participants included representatives from health professional organizations, labor unions, and concerned Federal Agencies. The purpose of this document is to report on the activities of the Project Group before, during, and since the October 1979 workshop; to publish the methodology and summary of the workshop; and to outline the type of recommendations expected to result from the workshop output.

Recommendations on Environmental and Occupational Education of Health Professionals, Project Group on Education of the Public and of Health Professionals, Ralph E. Yodaiken, Chairman, April 1980

The recommendations that resulted from a 2-day workshop on the environmental education needs of health professionals are presented in this document. These recommendations outline a strategy through which health professionals can more effectively prevent environment-related diseases. Included in the strategy are the establishment of an Interagency Education Program Liaison Group and specific recommendations addressing curriculum, faculty, students, continuing education, and research components.

A Comparison of Scientific and Procedural Bases Used by Federal Agencies for the Regulation of Carcinogens, February 13, 1980

This document is intended as an initial attempt to begin summarizing the risk assessment activities currently being conducted by Federal Agencies, interagency groups, scientific panels, and private groups in the field. A comparison of the scientific and procedural bases used by Federal Agencies for regulating carcinogenic substances is presented.

Directory of Federal Interagency Groups Concerned with Environmental Health, October 1979 and April 1980

First edition: October 1979. The document was compiled to enhance the availability of knowledge on environmental health. Information on 24 committees is included. The first edition, which is out of print, was superseded by a second edition.

Second edition: April 1980. This edition updated and expanded the information that was presented in the first edition. The second edition included information on 33 interagency committees and their subcommittees or components that deal with environmental health. Designed as a reference tool to locate interagency committees and their components, the Directory is intended to promote coordination and information exchange among the listed groups and the Agencies and institutions involved in identifying problems and initiating research in environment-related cancer and heart and lung disease.

Calendar, Monthly Issue

The Calendar was initiated in June 1979 and is distributed monthly to facilitate information dissemination within a 3-month time frame. The Calendar includes announcements of meetings, conferences, symposia, short courses, public hearings, and workshops that pertain to environmental pollution and disease.

Report of the Project Group on Exposure and Metabolic Mechanisms, April 1980

This report is a synthesis of discussions, ideas, literature searches, and proposed approaches for continuing activities of the Project Group. The Group's overall efforts are directed at establishing a mechanism to achieve interagency cooperation and developing recommendations for needed research in relating exposure to environmental pollutants, their human intake, toxicity, and metabolic fate. The Project Group enumerated nine areas where empirical research should continue.

Appendix D

DEFINITION OF CATEGORIES AND SUBCATEGORIES OF THE PROJECT INVENTORY

Appendix D

DEFINITION OF CATEGORIES AND SUBCATEGORIES OF THE PROJECT INVENTORY

Table D-1. Functional Groups and Categories

A. POLLUTANT IDENTIFICATION AND TRANSPORT

1. Identification and Monitoring of Environmental Pollutants

Research, identification, and measurement of the presence and concentrations of pollutants that may affect human health; includes characterization, chemical analysis, and monitoring of pollutants. Excluded is operational monitoring for regulatory purposes.

2. Identification and Analysis of Sources

Investigations of sources of environmental pollutants that may affect human health. Includes research on identifying and characterizing sources from which a specific pollutant is emitted, as well as the manner and amount of release of a pollutant from a source.

3. Environmental Transport and Transformation Analysis

Studies that predict environmental concentrations of a pollutant based on understanding of its transport processes and the physical or chemical changes that occur during such transport. Primary tools in such studies are analytical or physical models of environmental transport and transformation.

4. Development of Sampling, Analytic, and Monitoring Methods

Research to improve and refine methods and equipment involved in sampling, laboratory analysis, and monitoring equipment development.

B. HUMAN EFFECTS

5. Biological Effects

Investigations that examine the nature and range of biological effects associated with pollutants, including mode of entry of environmental pollutants into the human body, their metabolic pathways, target organs/toxin endpoints, residence times, and dose-response relationships.

(Continued)

Table D-1. Functional Groups and Categories (Continued)

B. HUMAN EFFECTS (Concluded)

6. Human Exposure Estimates

Statistical, modeling, and actual human exposure studies that estimate the level of exposure of individuals to pollution and the number of individuals exposed to a pollutant.

7. Epidemiology

Research concerned with defining and explaining the interrelationships of the environment with host and agent in causing environment-related disease.

C. RISKS AND COSTS

8. Population Risk Assessment

Studies which relate data on human exposure to pollutants with human diseases to estimate the risk of the health of populations that are exposed to such pollutants.

9. Costs of Environment-Related Illness

Investigations of the direct and indirect economic impact of environment-related disease, including evaluations of human morbidity and mortality costs and estimates of future health care costs that would be avoided if pollution were reduced.

10. Costs of Control and Prevention

Studies of the economic costs of implementing pollution control and preventive health programs.

D. RISK REDUCTION MEASURES

11. Education of Health Professionals and the Public

Programs directed toward improving the ability of the medical student and medical professional to recognize and treat environmental disease, efforts to educate the general public about environmental hazards and diseases as a means of prevention of environment-caused illness, and transfer of preventive measures and control technologies to industry.

(Continued)

Table D-1. Functional Groups and Categories (Concluded)

D. RISK REDUCTION MEASURES (Concluded)

12. Preventive Health

Programs designed to minimize the harmful effects of exposure to pollutants; excludes education and pollutant control programs.

13. Pollutant Control Measures

Efforts aimed at reducing pollutant levels, including development and evaluation of improved pollution control technologies and alteration of pollutant emission patterns.

Table D-2. Subcategories

A. POLLUTANT IDENTIFICATION AND TRANSPORT

1. Identification and Monitoring of Environmental Pollutants

a. Monitoring and Sampling
b. Analysis

Projects in Category 1 are divided into those involving direct sampling or monitoring of pollutants and those necessitating analytical work to identify, extract, or quantify a particular pollutant or toxic within a larger sampling.

2. Identification and Analysis of Sources

a. Municipal
b. Industrial
c. Residential
d. Transportation

Projects are sorted into the four types of sources listed above. Agricultural sources are considered to be industrial.

3. Environmental Transport and Transformation Analysis

a. Air
b. Water
c. Solids

These represent the three possible phases of pollutant transport and transformation.

4. Development of Sampling, Analytic, and Monitoring Methods

a. Sampling and Analysis
b. Monitoring

Method development is divided into sampling, analysis, and monitoring, as in Category 1.

(Continued)

Table D-2. Subcategories (Continued)

B. HUMAN EFFECTS

5. Biological Effects

a. Chemical Agents--Genetic/Molecular Level
b. Chemical Agents--Biochemical Level
c. Chemical Agents--Organ Level
d. Chemical Agents--Whole-body Level or Unspecified
e. Structural Toxins--Genetic/Molecular Level
f. Structural Toxins--Biochemical Level
g. Structural Toxins--Organ Level
h. Structural Toxins--Whole-body Level or Unspecified
i. Techniques

Biological effects, with one exception, are viewed from the perspective of an agent causing physiological change in man or other organisms. Such agents are divided into chemical agents, which act biochemically on the organism, and structural toxins, which cause damage by virtue of their structure (e.g., inhalable particulates, fibers). Within the two classes of toxins, projects are divided according to the level of activity of the agents. The Genetic/Molecular Level is concerned with DNA-level studies, the Biochemical Levels primarily with metabolic studies. Organ Level studies include cell culture and target organ research not concerned with metabolism; Whole-body Level or Unspecified work is self-explanatory. The last subcategory, Techniques, includes methodology development such as bioassays.

6. Human Exposure Estimates

a. Concentration Levels of Exposure--Occupational
b. Concentration Levels of Exposure--General Public
c. Population Numbers Exposed--Occupational
d. Population Numbers Exposed--General Public

The subcategories are divided into studies estimating the concentration levels of a toxin that a person is exposed to, and the number of people exposed to a toxin at a particular concentration level. Within each group, occupational and nonoccupational studies are separated.

(Continued)

Table D-2. Subcategories (Continued)

B. HUMAN EFFECTS (Concluded)

7. Epidemiology

a. Case Control and Cohort Studies--Occupational
b. Case Control and Cohort Studies--General Public
c. Laboratory Studies
d. Statistical Support
e. National Probability Surveys or Records Systems

Epidemiology studies are divided into four groups: field studies (in turn divided into occupational and nonoccupational studies), laboratory studies, statistical support and methodology development, and surveys.

C. RISKS AND COSTS

8. Population Risk Assessment

a. Occupational
b. General Public

Studies in Category 8 are separated on the basis of occupational and nonoccupational settings.

9. Costs of Environment-Related Illness

No subcategories are needed for this category.

10. Costs of Control and Prevention

a. Costs of Pollution Control
b. Costs of Preventive Health

Studies in Costs of Control and Prevention are divided into those dealing with the costs of pollution control technologies and those dealing with the costs of preventive health programs.

(Continued)

Table D-2. Subcategories (Concluded)

D. RISK REDUCTION MEASURES

11. Education of Health Professionals and the Public

a. General Public
b. Health Professionals
c. Education Institutions
d. Technology Transfer to Industry

The subcategories of the education category are based on the intended audiences: the general public, health professionals in continuing education programs, students attending school, and industry. The first three subcategories are concerned with health issues, and the last subcategory with pollution control technologies.

12. Preventive Health

a. Detection Methodologies Development--Individuals
b. Detection Methodologies Development--Populations
c. Screening for Risk

Preventive health programs are divided into studies of new methodologies and actual screening programs. Methodology development is in turn separated into research of new tests applicable to individuals and new tests applicable to whole populations (as the lowest common unit of examination).

13. Pollutant Control Measures

a. Alteration of Production or Emission Patterns--Development
b. Alteration of Production or Emission Patterns--Evaluation
c. Add-on Technologies--Development
d. Add-on Technologies--Evaluation

Research into Pollutant Control Measures is separated into technologies that are added onto an existing process and those that change the process itself. Each group is divided in turn into the development of new measures and their evaluation.

Appendix E

MEETING DATES

Appendix E

MEETING DATES

TASK FORCE PLENARY

April 15, 1981

WORKING GROUP

September 16, 1980
October 9, 1980
December 17, 1980
January 21, 1981
March 4, 1981
May 28, 1981
July 2, 1981

PROJECT GROUP ON EDUCATION OF THE PUBLIC AND OF HEALTH PROFESSIONALS

June 25, 1980 (Education of the Public)
August 14, 1980 (Public)
September 9, 1980 (Public)
November 5, 1980 (Education of the Professionals)
November 19, 1980 (Public)
December 10, 1980 (Public)
December 16, 1980 (Professionals)
February 17, 1981 (Professionals)
March 11, 1981 (Public)
April 14, 1981 (Professionals)
April 15, 1981 (Public)

PROJECT GROUP ON STANDARDIZATION OF MEASUREMENTS AND TESTS

June 2, 1980
December 15, 1980
March 2, 1981

PROJECT GROUP ON EXPOSURE AND METABOLIC MECHANISMS*

July 22, 1980
September 9, 1980
October 31, 1980
November 10, 1980
November 14, 1980
November 19, 1980
November 25, 1980
January 15, 1981
January 27-30, 1981**
February 20, 1981
June 26, 1981

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* These were meetings of either the full Project Group, local Project Group members, or Workshop Planning Committee members. Information from subcommittee meetings was mailed to all Project Group members for review and comments.

** Workshop on Exposure, Metabolism, and Mechanisms of Toxicity.

PROPOSED MEETING DATES FOR 1981-82

Meeting	Day and Dates
Working Group	Wednesday, September 16, 1981
Working Group	Wednesday, November 19, 1981
Working Group	Wednesday, January 20, 1982
Working Group	Wednesday, March 3, 1982
Task Force Plenary	Wednesday, April 14, 1982
Working Group	Thursday, May 27, 1982
Working Group	Thursday, July 1, 1982